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(54) METHOD FOR REPURPOSING NDC CODES IN A PHARMACEUTICAL DATABASE FOR VENOM DERIVED ALLERGENS INVOLVED IN VENOM IMMUNOTHERAPY

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(60) Provisional application No. 62/169,787, filed on Jun. 2, 2015, provisional application No. 62/169,785, filed on Jun. 2, 2015, provisional application No. 62/203,819, filed on Aug. 11, 2015, provisional application No. 62/349,626, filed on Jun. 13, 2016.

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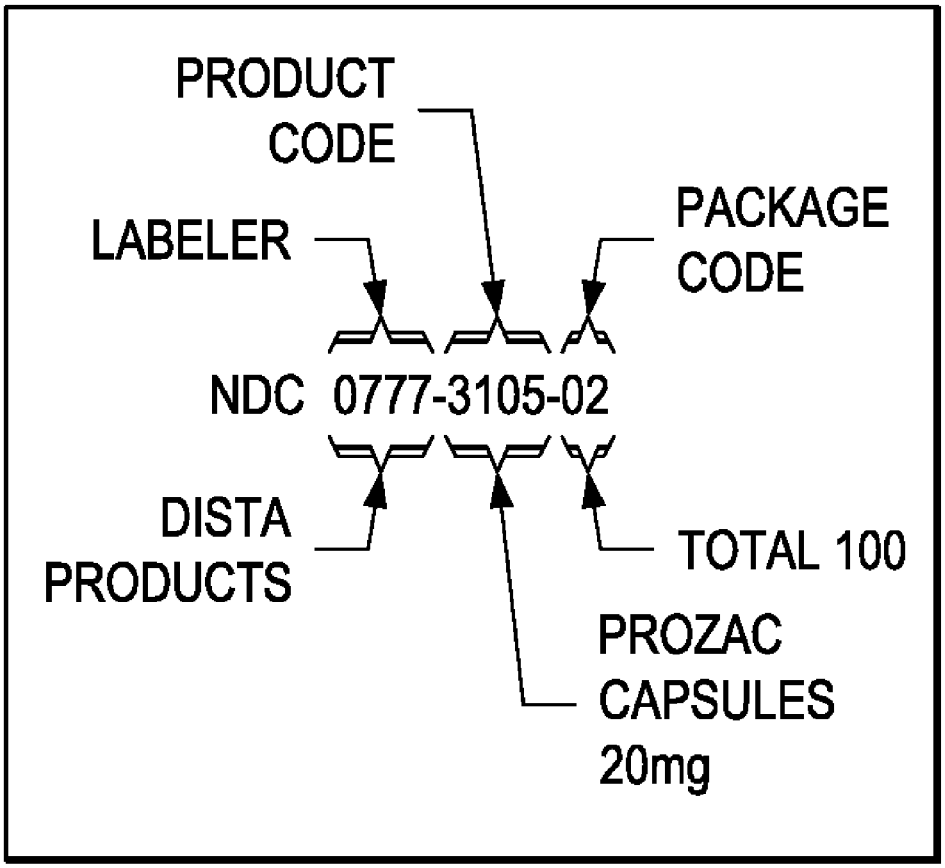
(52) **U.S. Cl.**
CPC *G06F 19/328* (2013.01)

(57) **ABSTRACT**

A method for adjudicating reimbursement for venom derived allergens between a pharmacist and a reimbursing entity comprises obtaining National Drug Codes (NDC's) for a plurality of venom derived allergens, storing in a central control database the obtained NDC's in association with an associated AWP and associated information for the venom derived allergen, which associated information includes translation information to allow practitioners to determine from a desired diluted level and number of doses of a desired NDC carrying venom derived antigen and a known dilution procedure how to translate back to the amount of base concentration of the NDC carrying venom derived antigen used to create the desired diluted level and number of doses, and determining if any of the NDC's in the central control database are contained within the third-party database and, if not, transferring the associated NDC's not in the third-party database to the third-party database.



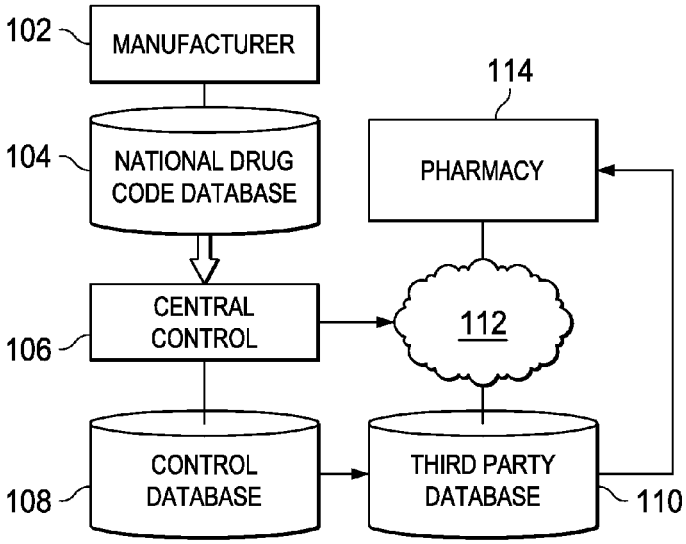


FIG. 1

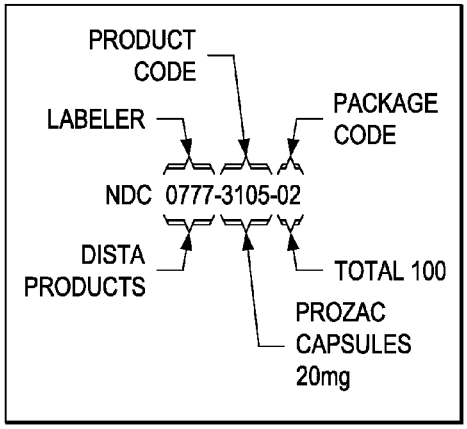


FIG. 1A

THIRD PARTY DATABASE

NATIONAL DRUG CODE	AVERAGE WHOLESALE PRICE	INFORMATION	
XX.XX	$4.44	AAA	
YY.YY	$5.44	BBB	
ZZ.ZZ	$6.44	CCC	

FIG. 2

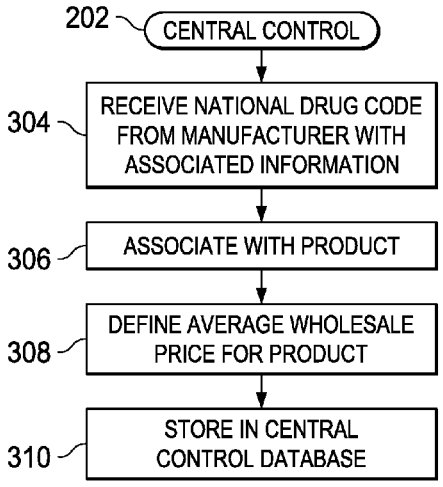


FIG. 3

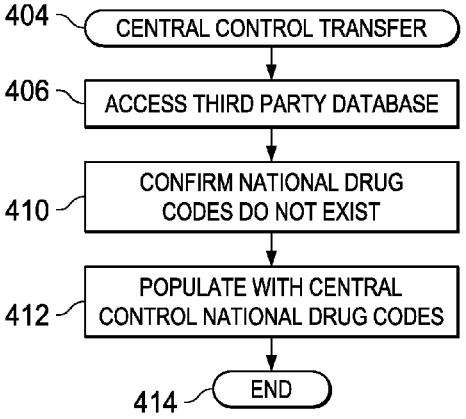


FIG. 4

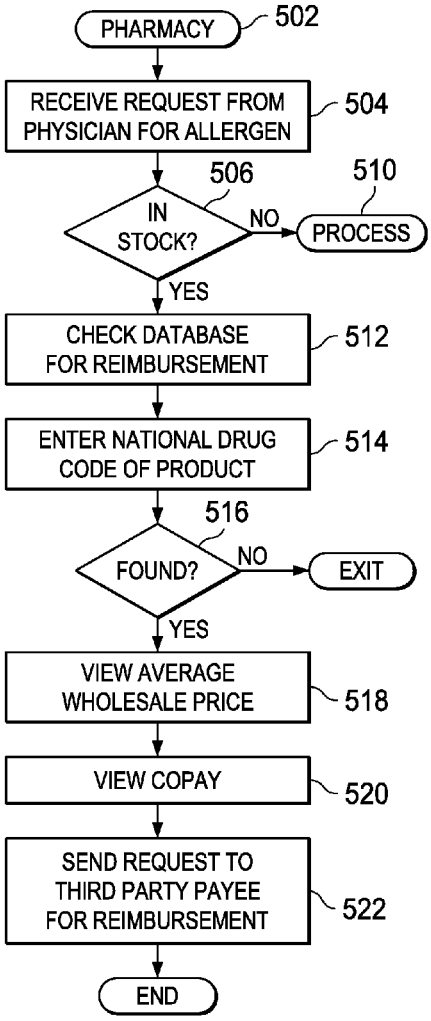


FIG. 5

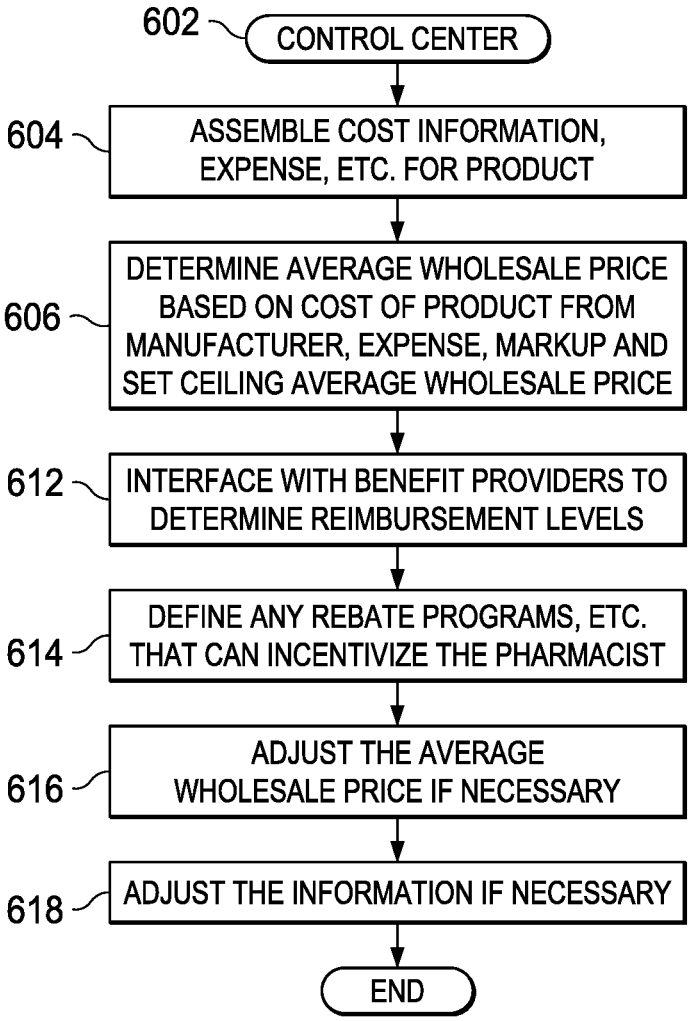

602
CONTROL CENTER
604
ASSEMBLE COST INFORMATION, EXPENSE, ETC. FOR PRODUCT
606
DETERMINE AVERAGE WHOLESALE PRICE BASED ON COST OF PRODUCT FROM MANUFACTURER, EXPENSE, MARKUP AND SET CEILING AVERAGE WHOLESALE PRICE
612
INTERFACE WITH BENEFIT PROVIDERS TO DETERMINE REIMBURSEMENT LEVELS
614
DEFINE ANY REBATE PROGRAMS, ETC. THAT CAN INCENTIVIZE THE PHARMACIST
616
ADJUST THE AVERAGE WHOLESALE PRICE IF NECESSARY
618
ADJUST THE INFORMATION IF NECESSARY
END

FIG. 6

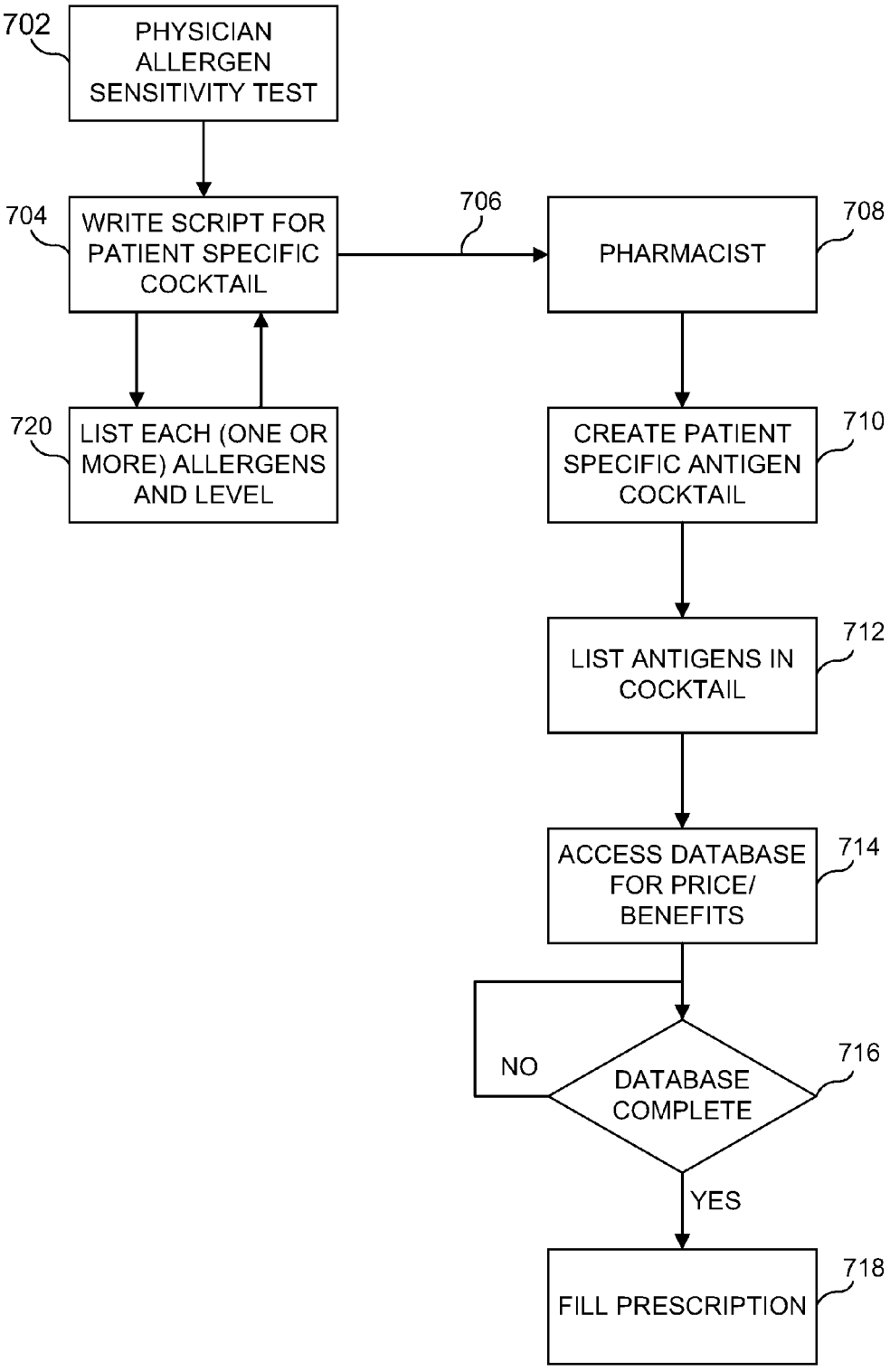

702
PHYSICIAN ALLERGEN SENSITIVITY TEST
704
WRITE SCRIPT FOR PATIENT SPECIFIC COCKTAIL
706
PHARMACIST
708
720
LIST EACH (ONE OR MORE) ALLERGENS AND LEVEL
CREATE PATIENT SPECIFIC ANTIGEN COCKTAIL
710
LIST ANTIGENS IN COCKTAIL
712
ACCESS DATABASE FOR PRICE/ BENEFITS
714
NO
DATABASE COMPLETE
716
YES
FILL PRESCRIPTION
718

FIG. 7

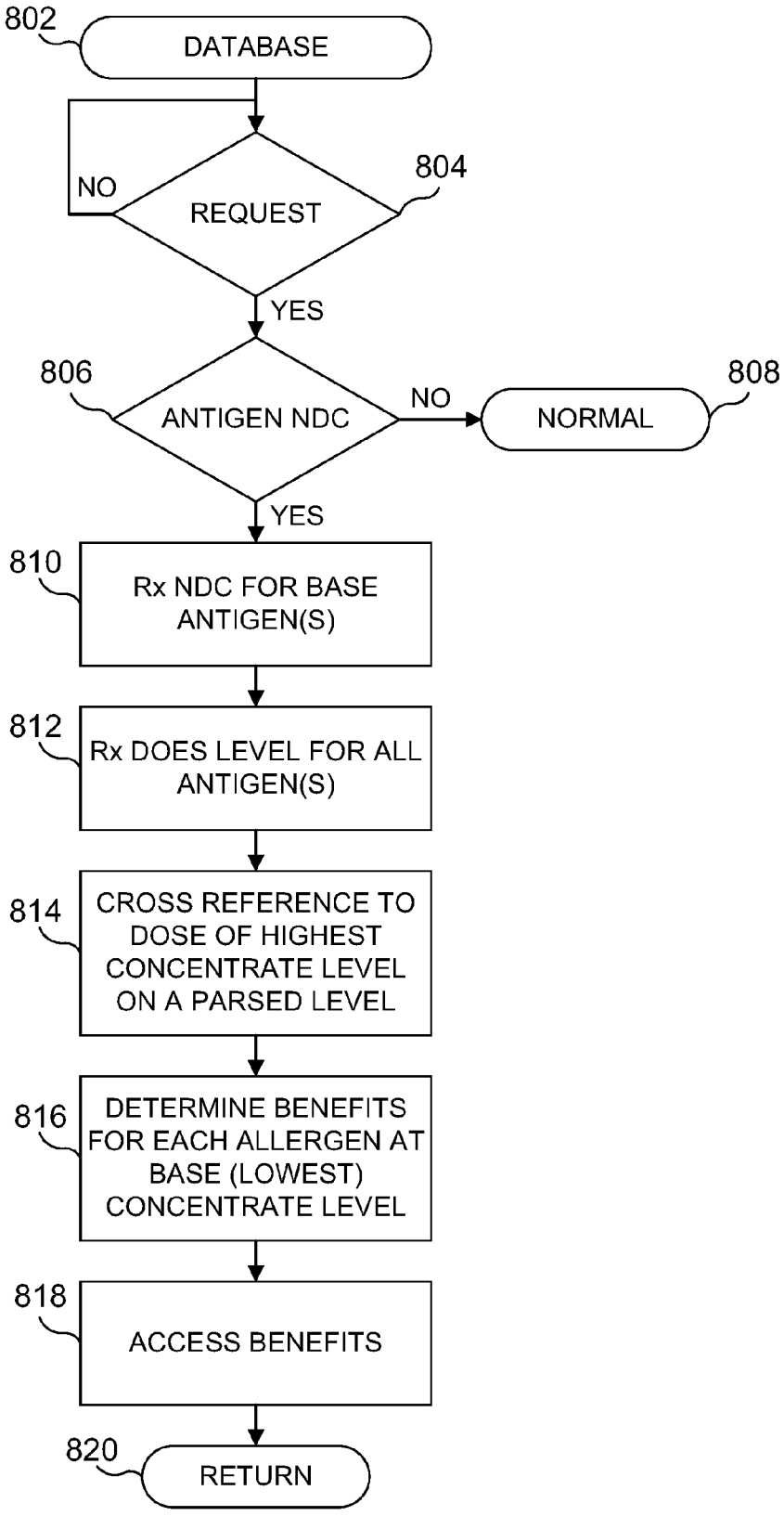

802
DATABASE
804
NO
REQUEST
YES
806
ANTIGEN NDC
NO
808
NORMAL
YES
810
Rx NDC FOR BASE ANTIGEN(S)
812
Rx DOES LEVEL FOR ALL ANTIGEN(S)
814
CROSS REFERENCE TO DOSE OF HIGHEST CONCENTRATE LEVEL ON A PARSED LEVEL
816
DETERMINE BENEFITS FOR EACH ALLERGEN AT BASE (LOWEST) CONCENTRATE LEVEL
818
ACCESS BENEFITS
820
RETURN

FIG. 8

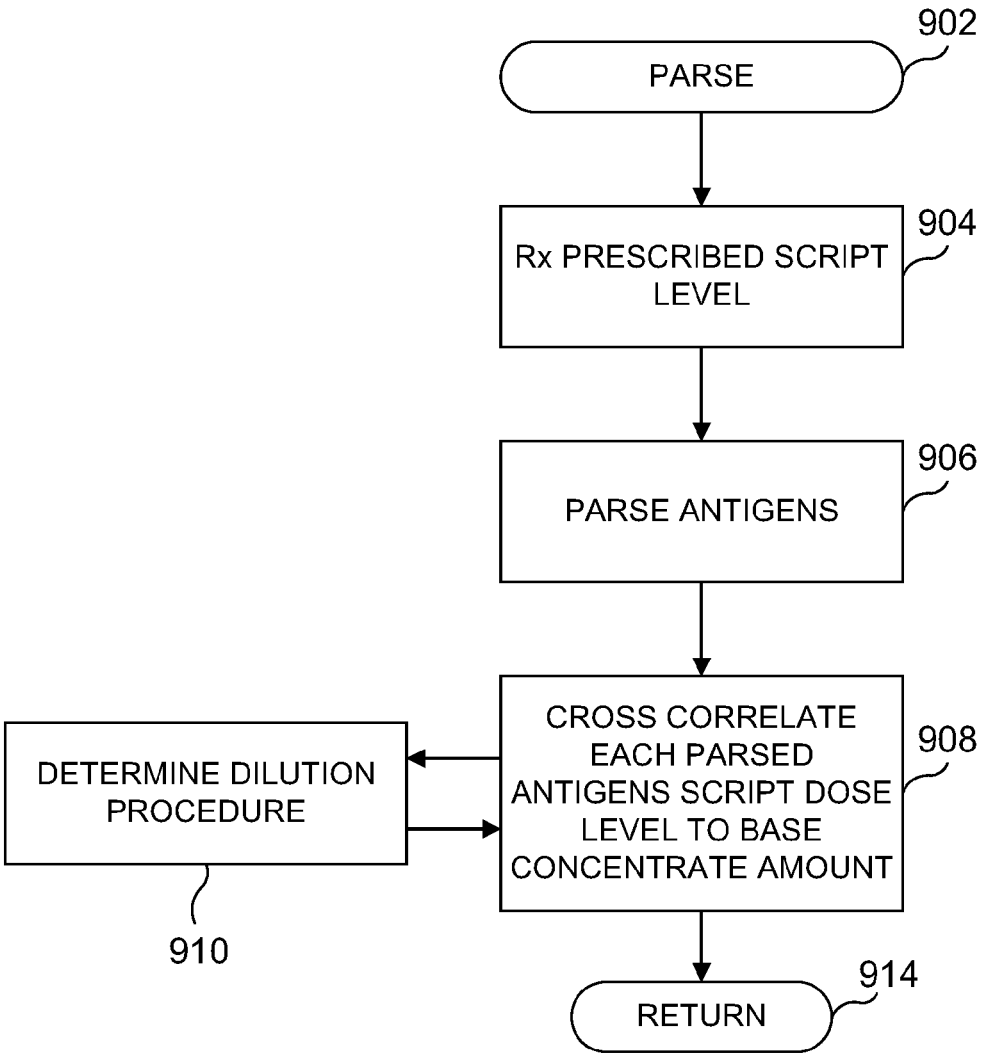

902
PARSE
904
Rx PRESCRIBED SCRIPT LEVEL
906
PARSE ANTIGENS
908
CROSS CORRELATE EACH PARSED ANTIGENS SCRIPT DOSE LEVEL TO BASE CONCENTRATE AMOUNT
DETERMINE DILUTION PROCEDURE
910
914
RETURN

FIG. 9

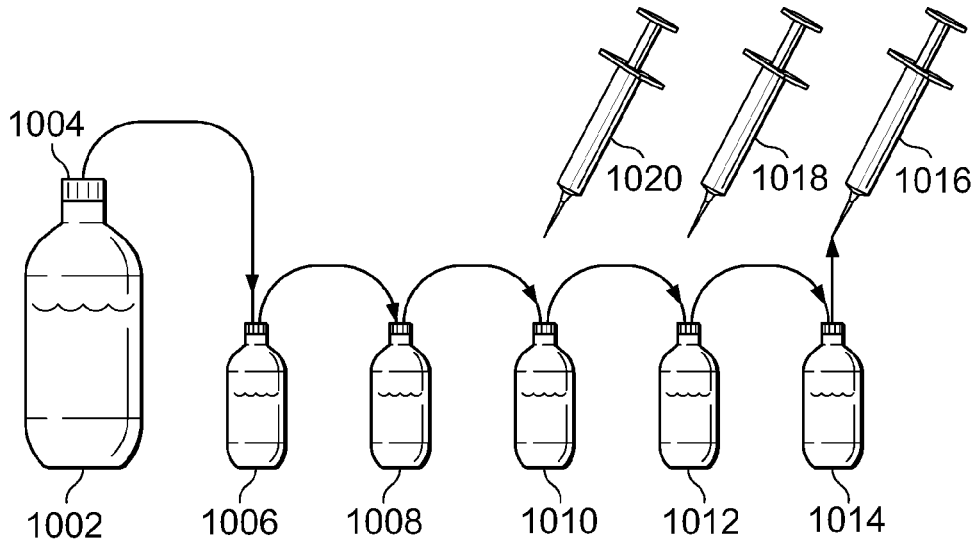


FIG. 10

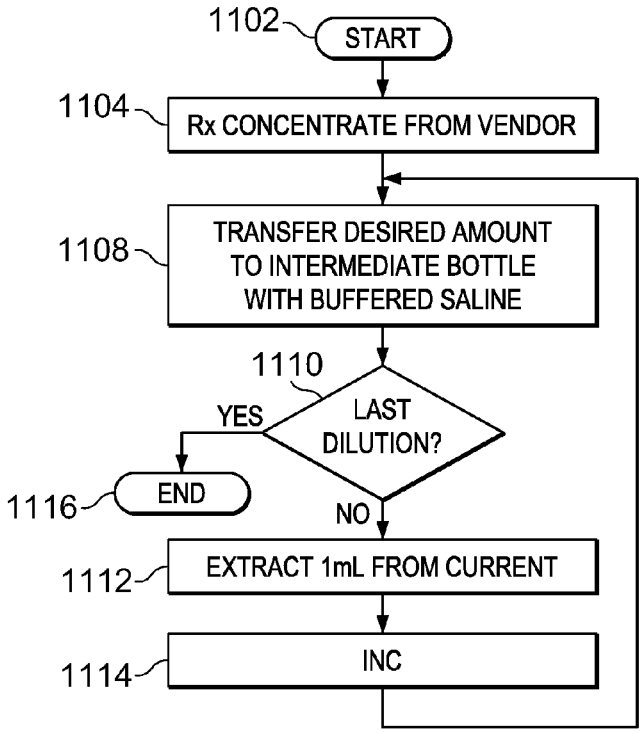

1102
START
1104
Rx CONCENTRATE FROM VENDOR
1108
TRANSFER DESIRED AMOUNT TO INTERMEDIATE BOTTLE WITH BUFFERED SALINE
1110
LAST DILUTION?
YES
NO
1116
END
1112
EXTRACT 1mL FROM CURRENT
1114
INC

FIG. 11

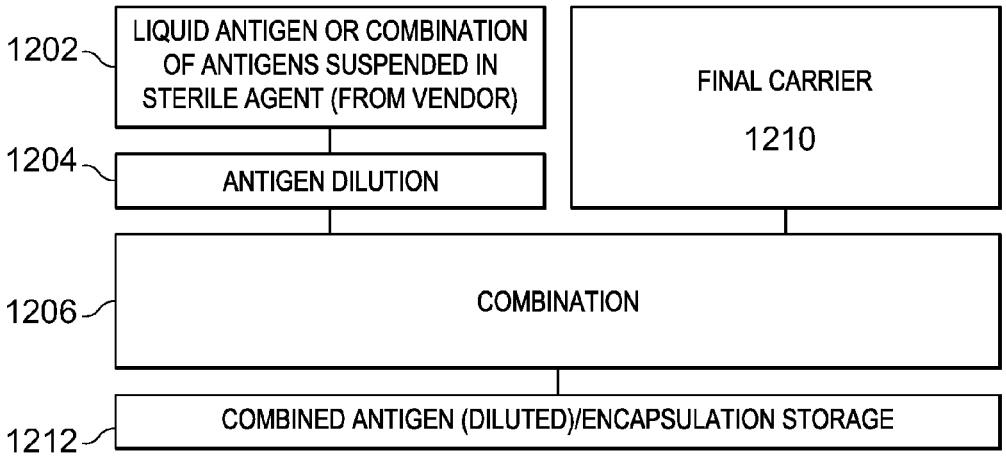

1202
LIQUID ANTIGEN OR COMBINATION OF ANTIGENS SUSPENDED IN STERILE AGENT (FROM VENDOR)
1204
ANTIGEN DILUTION
FINAL CARRIER
1210
1206
COMBINATION
1212
COMBINED ANTIGEN (DILUTED)/ENCAPSULATION STORAGE

FIG. 12

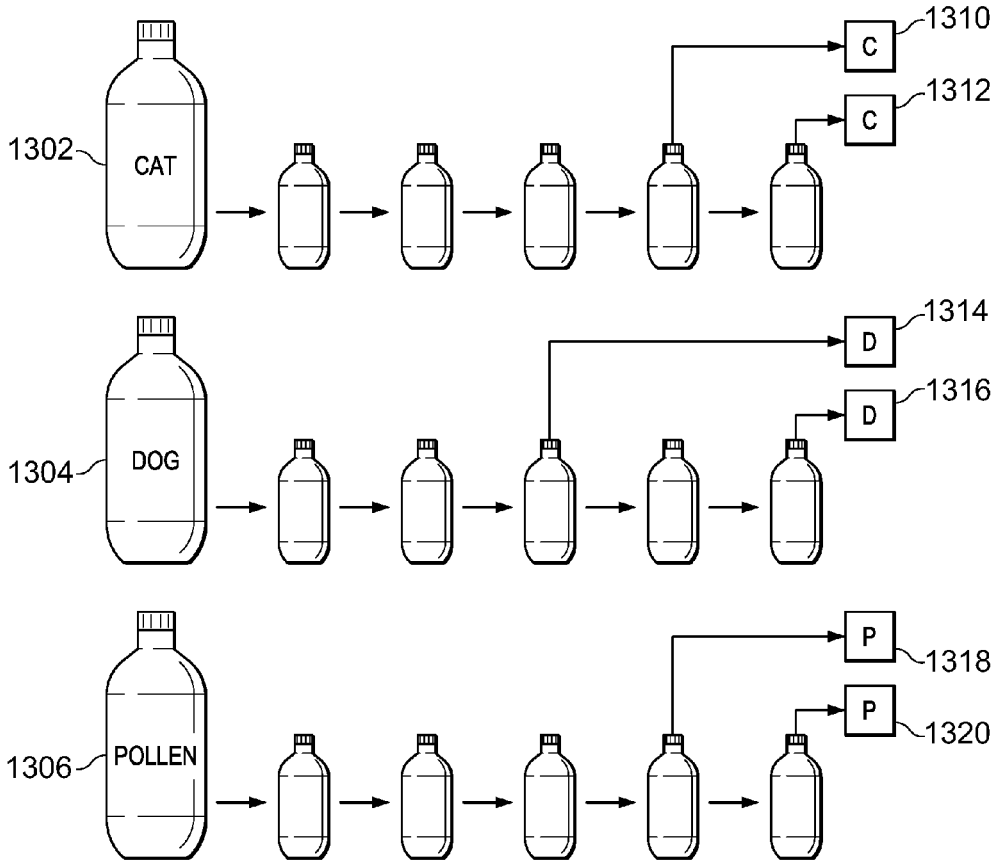

1302
CAT
1304
DOG
1306
POLLEN
C
C
D
D
P
P
1310
1312
1314
1316
1318
1320

FIG. 13

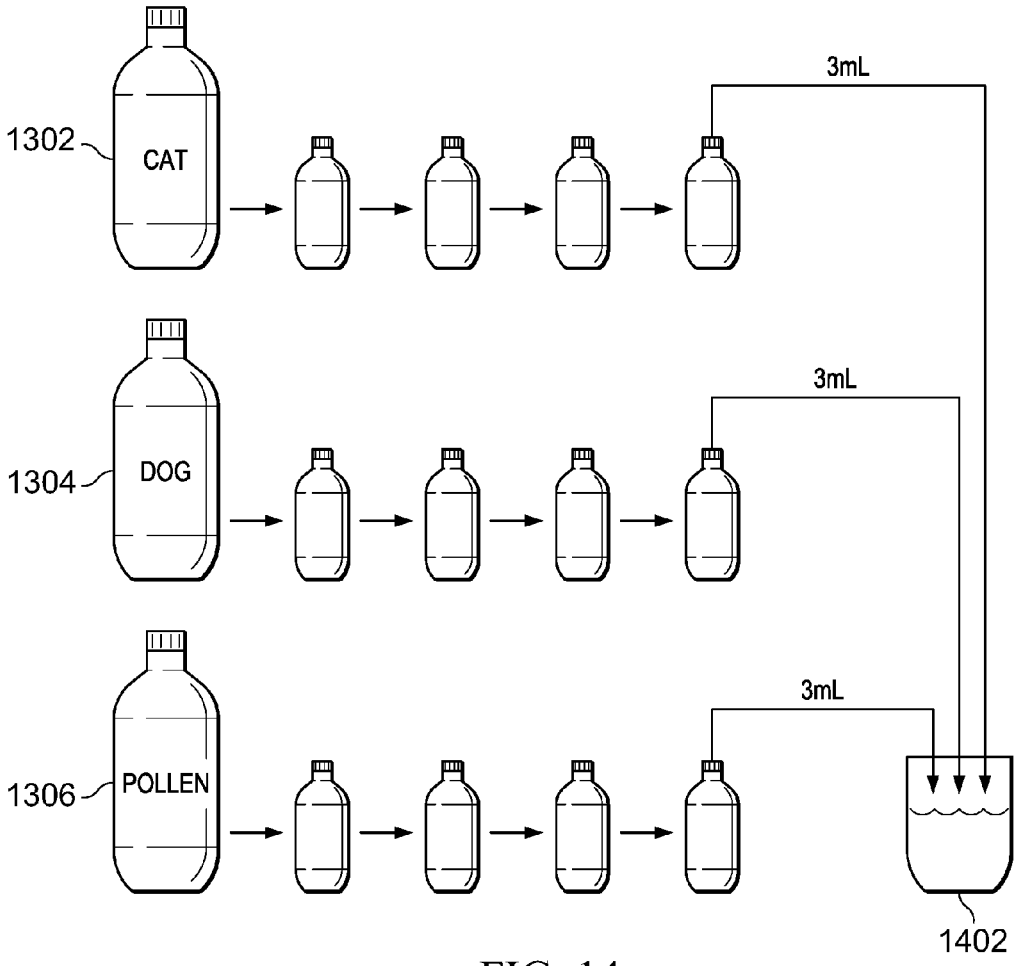


FIG. 14

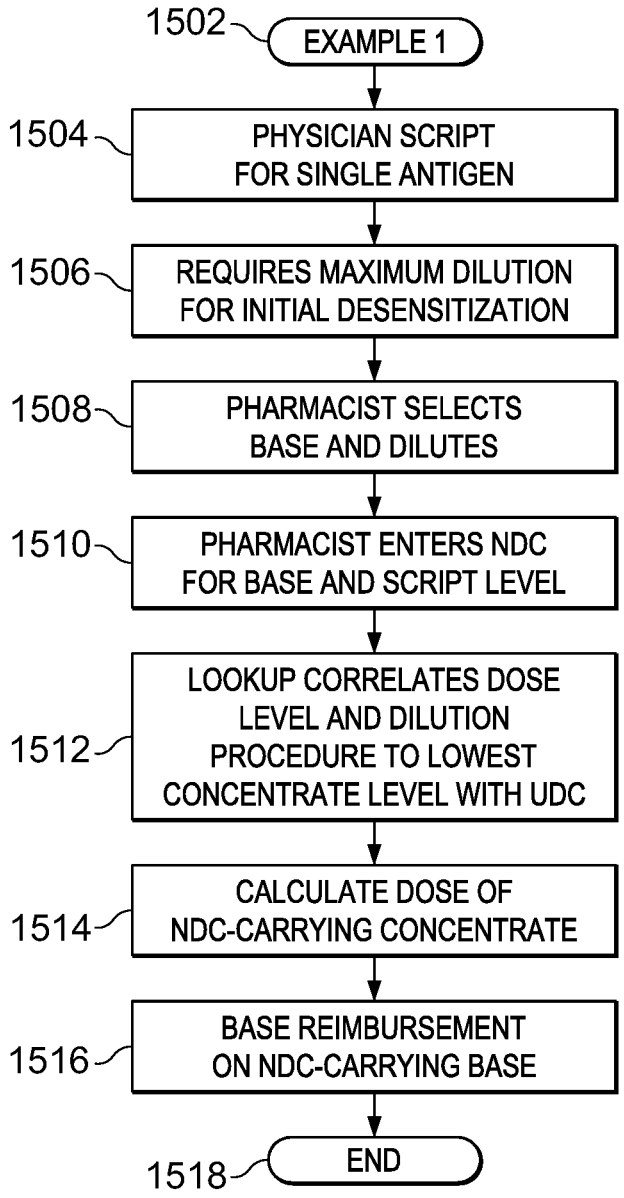

1502
EXAMPLE 1
1504
PHYSICIAN SCRIPT FOR SINGLE ANTIGEN
1506
REQUIRES MAXIMUM DILUTION FOR INITIAL DESENSITIZATION
1508
PHARMACIST SELECTS BASE AND DILUTES
1510
PHARMACIST ENTERS NDC FOR BASE AND SCRIPT LEVEL
1512
LOOKUP CORRELATES DOSE LEVEL AND DILUTION PROCEDURE TO LOWEST CONCENTRATE LEVEL WITH UDC
1514
CALCULATE DOSE OF NDC-CARRYING CONCENTRATE
1516
BASE REIMBURSEMENT ON NDC-CARRYING BASE
1518
END

FIG. 15

SINGLE ANTIGEN TABLE								
NDC	ANTIGEN	DILUTION PROCEDURE	D1 (BASE)	D2	D3	D4	D5	D6
XXX	CAT	STANDARD	X1	X2	X3	X4	X5	X6
			Y1	Y2	Y3	Y4	Y5	Y6
			Z1	Z2	Z3	Z4	Z5	Z6
⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
YYY	DOG	STANDARD	X1	X2	X3	X4	X5	X6
			Y1	Y2	Y3	Y4	Y5	Y6
			Z1	Z2	Z3	Z4	Z5	Z6
⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮

FIG. 16

DILUTION PROCEDURE	D1	D2	D3	D4	D5	D6
S1	Z1	Z2	Z3	Z4	Z5	Z6
S2	Z1'	Z2'	Z3'	Z4'	Z5'	Z6'
S3	Z1"	Z2"	Z3"	Z4"	Z5"	Z6"

FIG. 16A

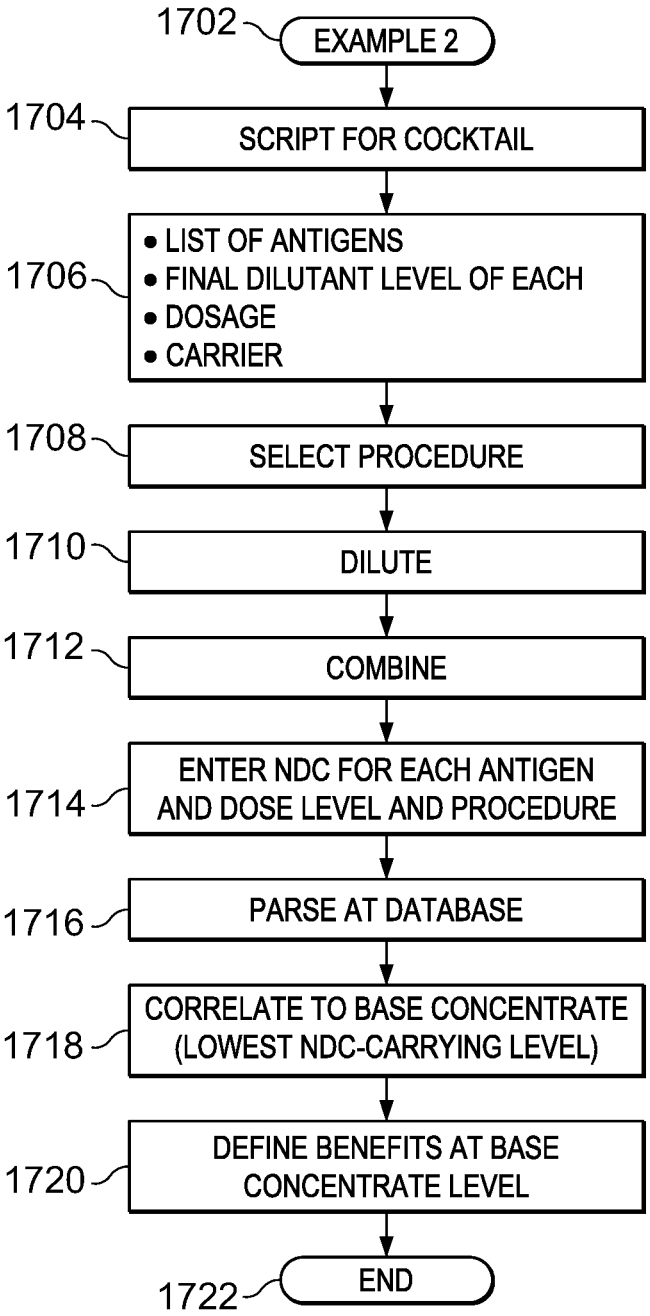

1702
EXAMPLE 2
1704
SCRIPT FOR COCKTAIL
1706
• LIST OF ANTIGENS
• FINAL DILUTANT LEVEL OF EACH
• DOSAGE
• CARRIER
1708
SELECT PROCEDURE
1710
DILUTE
1712
COMBINE
1714
ENTER NDC FOR EACH ANTIGEN AND DOSE LEVEL AND PROCEDURE
1716
PARSE AT DATABASE
1718
CORRELATE TO BASE CONCENTRATE (LOWEST NDC-CARRYING LEVEL)
1720
DEFINE BENEFITS AT BASE CONCENTRATE LEVEL
1722
END

FIG. 17

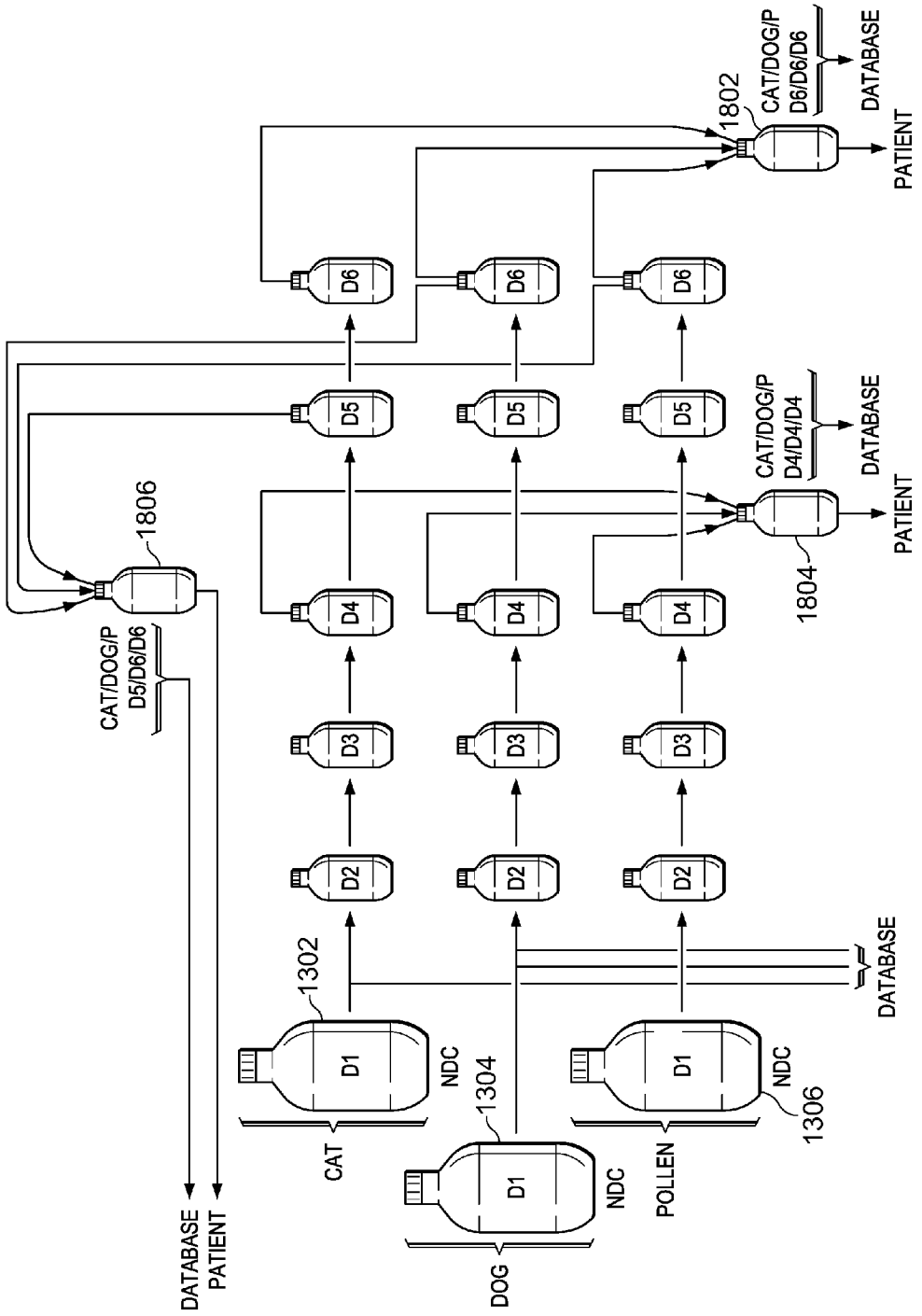

1802
CAT/DOG/P
D6/D6/D6
DATABASE
PATIENT
D6
D5
CAT/DOG/P
D4/D4/D4
DATABASE
PATIENT
1804
1806
D4
CAT/DOG/P
D5/D6/D6
D3
D2
1302
DATABASE
D1
NDC
1304
1306
CAT
DOG
POLLEN
DATABASE
PATIENT

FIG. 18

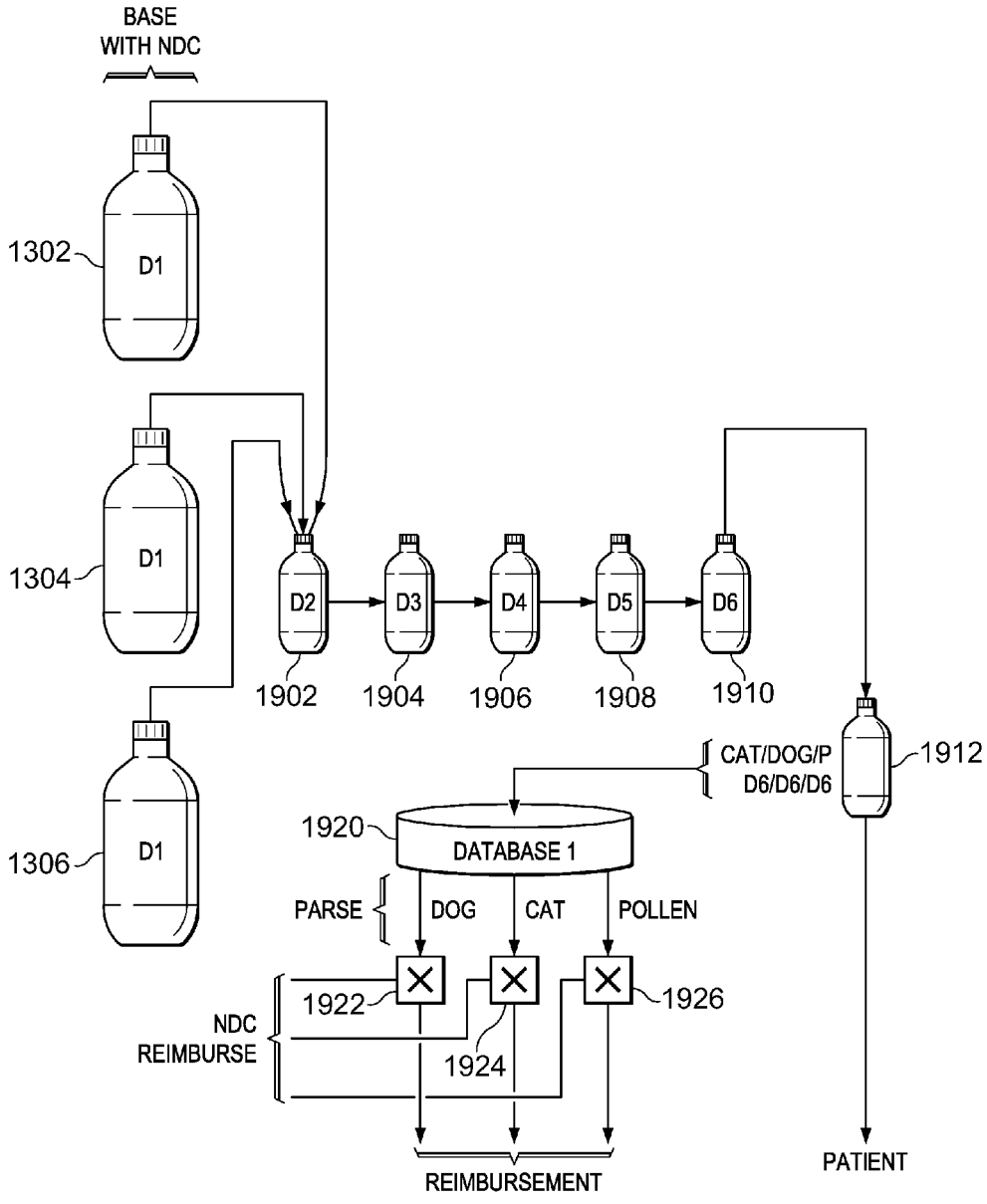

BASE
WITH NDC
1302
D1
1304
D1
1306
D1
D2
D3
D4
D5
D6
1902
1904
1906
1908
1910
CAT/DOG/P
D6/D6/D6
1912
1920
DATABASE 1
PARSE
DOG
CAT
POLLEN
1922
1926
NDC
REIMBURSE
1924
REIMBURSEMENT
PATIENT

FIG. 19

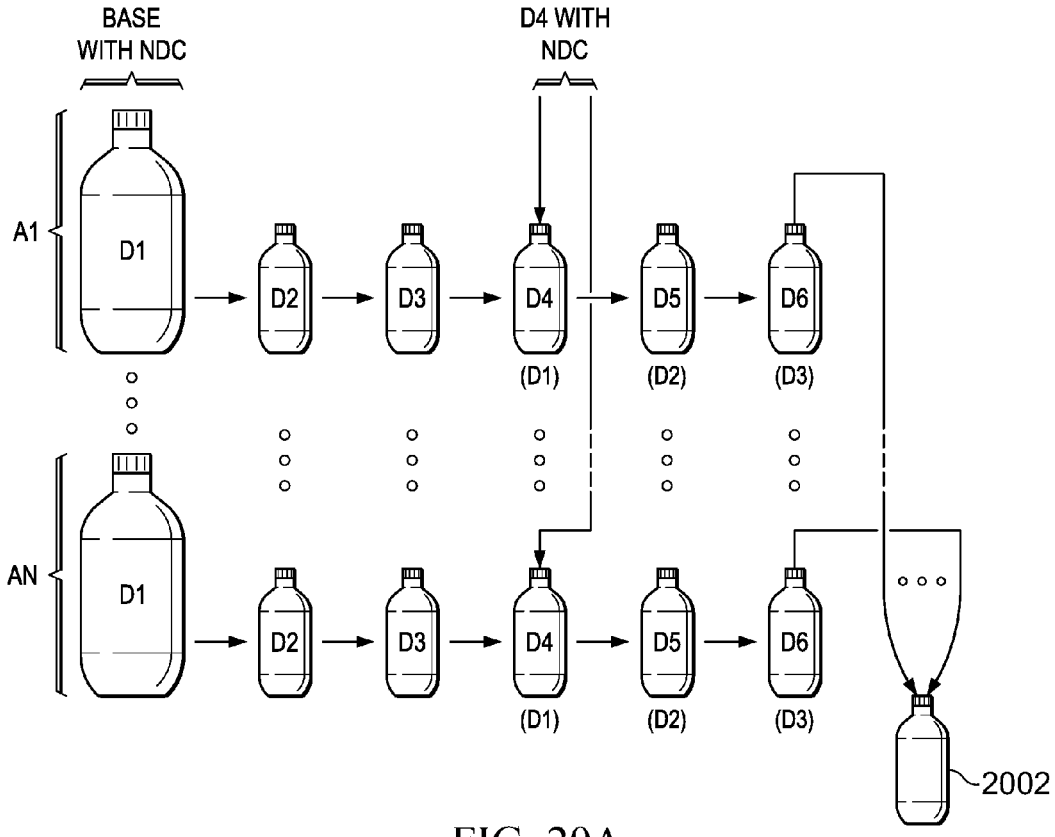


FIG. 20A

NDC BASE	ANTIGEN	DILUTION PROCEDURE	D1 (D4)	D2 (D5)	D3 (D6)	D4
XXX	A1	STANDARD	X1	X2	X3	A1
⋮	⋮	⋮	⋮	⋮	⋮	⋮

FIG. 20B

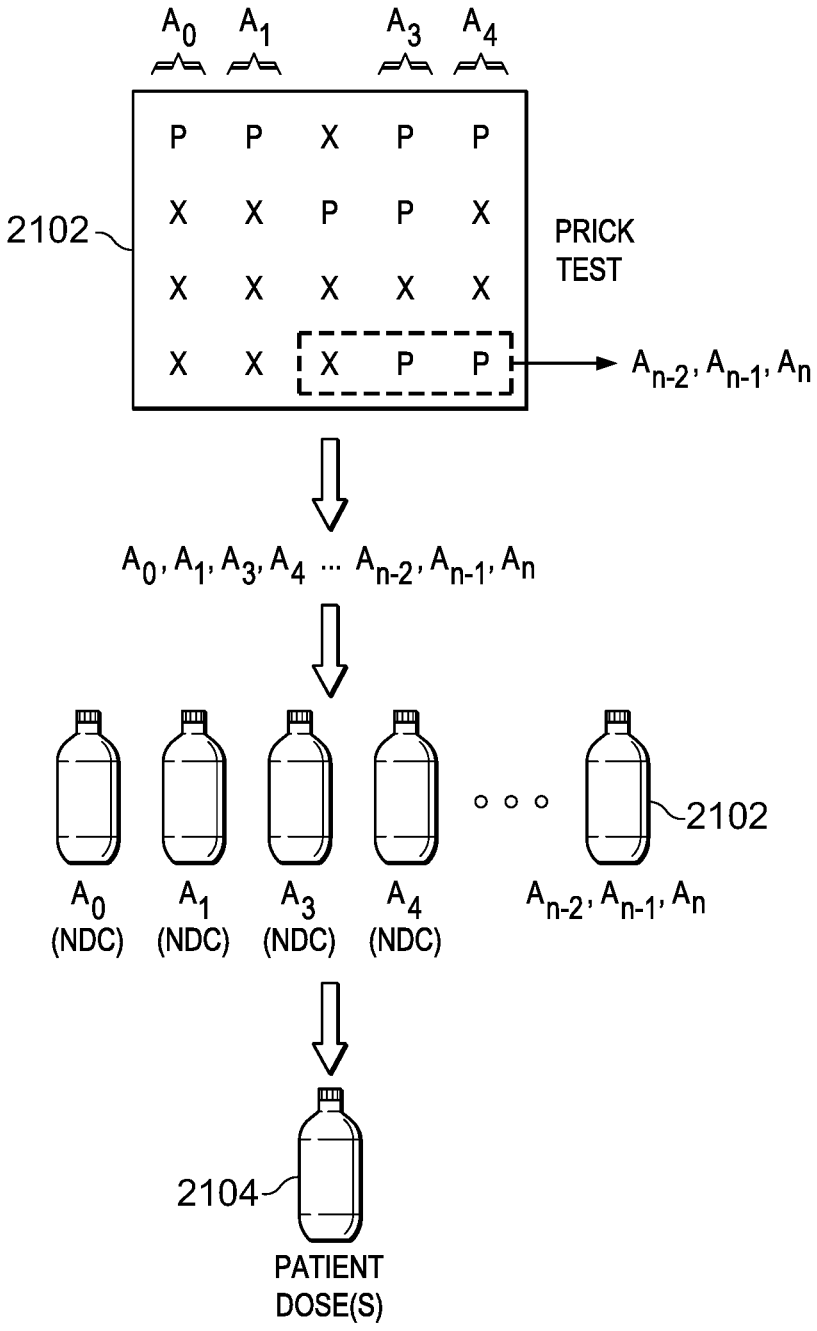

A0 A1 A3 A4
P P X P P
X X P P X
X X X X X
X X X P P
2102
PRICK TEST
An-2, An-1, An
A0, A1, A3, A4 ... An-2, An-1, An
2102
A0 (NDC)
A1 (NDC)
A3 (NDC)
A4 (NDC)
An-2, An-1, An
2104
PATIENT DOSE(S)

FIG. 21

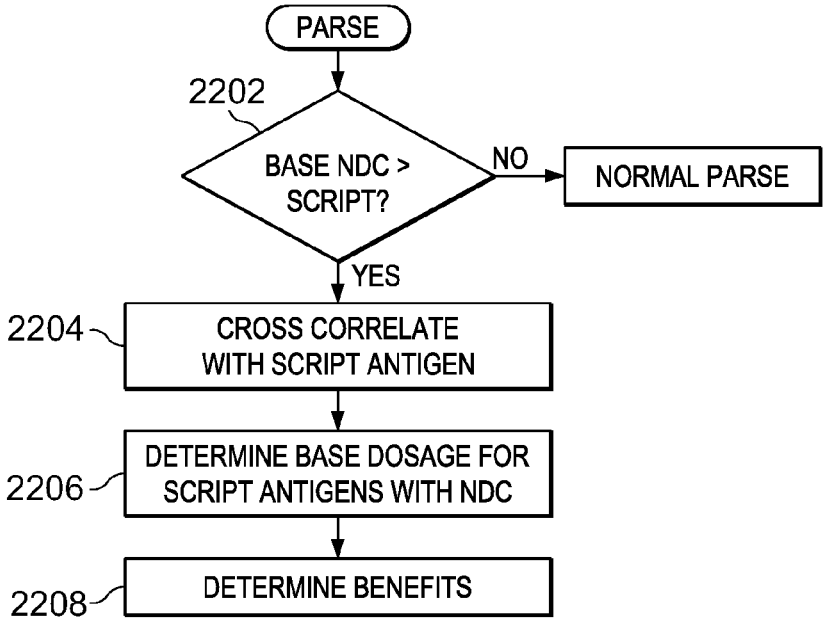


FIG. 22A

NDC BASE	ANTIGEN	DILUTION PROCEDURE	D1	D2	D3	D4	D5	D6
XXX (1702)	A_{n-2}	STANDARD	X_1	X_1	X_1	X_1	X_1	X_1
	A_{n-1}		X_1	X_1	X_1	X_1	X_1	X_1
	A_n		X_1	X_1	X_1	X_1	X_1	X_1
⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮

FIG. 22B

METHOD FOR REPURPOSING NDC CODES IN A PHARMACEUTICAL DATABASE FOR VENOM DERIVED ALLERGENS INVOLVED IN VENOM IMMUNOTHERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation-in-Part application of U.S. patent application Ser. No. 15/171,920, filed Jun. 2, 2016, entitled METHOD FOR MANAGING REIMBURSEMENTS FOR PREVIOUSLY NON DATABASE ALLERGENS (Atty. Dkt. No. RCMD-33164), which claims the benefit of U.S. Provisional Application No. 62/169,787, filed on Jun. 2, 2015, entitled METHOD FOR REPURPOSING NDC CODES IN A PHARMACEUTICAL DATABASE FOR ALLERGENS (Atty. Dkt. No. RCMD-32681), and U.S. Provisional Application No. 62/169,785, filed on Jun. 2, 2015, entitled METHOD FOR MANAGING REIMBURSEMENTS FOR PREVIOUSLY NON DATABASE ALLERGENS (Atty. Dkt. No. RCMD-32682), the specifications of which are incorporated by reference in their entirety. This application also claims the benefit of U.S. Provisional Application No. 62/203,819, filed on Aug. 11, 2015, and entitled METHOD FOR REPURPOSING NDC CODES IN A PHARMACEUTICAL DATABASE FOR VENOM DERIVED ALLERGENS INVOLVED IN VENOM IMMUNOTHERAPY, which is herein incorporated by reference in its entirety. This application also claims the benefit of U.S. Provisional Application No. 62/349,626, filed on Jun. 13, 2016, entitled METHOD AND APPARATUS FOR COMPLETING PRESCRIPTION FOR ALLERGEN COCKTAIL WITH PATCH.

TECHNICAL FIELD

[0002] The following disclosure relates to repurposing an existing database related to the pharmaceutical industry and reimbursement for such things as allergens involved in venom immunotherapy that are not currently supported in the database or only a few of which are supported.

BACKGROUND

[0003] Immunotherapy basically involves a series of allergy shots given to reduce one's sensitivity to various allergens that may cause an allergic reaction. This immunotherapy can either be venom based or environmentally based. For venom based immunotherapy (VIT), treatments are available for allergies to stings such as honeybees, Yellowjackets, Hornets, paper wasps, fire ants and snakebites. For such things as insect stings, very small amount of the insect venom is injected under the skin in a dilute saline solution. This type of therapy is recommended for all patients who have experienced systemic reaction to insect sting and have specific IgE to venom allergens shown either my skin or blood test. Individuals with a history of a systemic reaction to an insect sting are at an increased risk of subsequent systemic sting reactions. VIT as compared to Environmental Immunotherapy is different than pollins and the such that one might be exposed to in the environment in that VIT is basically associated with allergens that are flown around inside a special injection device that, when counter, may threaten the lives of those who are sent to to it . . . . Insect venom allergy or snake venom. The primary offenders associated with VIT are prone primarily insects that sting rather than those that might or, as noted hereinabove, snakes. The insects that sting are typically members of the order of Hymenoptera of the class insect. This can include members of the Vespid family, Yellowjackets, yellow Hornets, white-faced Hornets and wasps. There also the class of Apids, including honeybees and bumblebees. There's also the Formicid family that consists of fire ants and Harvester ants.

[0004] To desensitize an individual against a particular venom, the process is to immunize the individual with small and graded doses of the venom. This is compared to the use of an anti-venom which is manufactured via a purified process in another animal such as a sheet. For example, the approved anti-venom for the pit viper (rattlesnake, copperhead and water moccasin) is based on a purified product made in sheet known as CroFab. These anti-venoms are typically administered through intravenous techniques. However, there are some antivenoms for such things as stonefish and redback spider that are administered intramuscularly. These antivenoms are injected after a bite, as they are designed to bind to and neutralize the venom, halting further damage, but do not reverse damage already done. This is compared to desensitizing an individual by small graded doses.

[0005] In general, and antigen is any structural substance that serves as a target for the receptors of an adaptive immune response or, alternatively, and more simply stated, and antigen is any substance that causes an immune system to produce antibodies against it. An allergen is a type of antigen that produces an abnormally vigorous immune response in which the immune system fights off a perceived threat that would otherwise be harmless to the body. These reactions are termed allergies. Thus, by providing small graded doses of venom as the allergen, this would produce some type of immune response in the immune system that would generate anti-bodies to fight off the perceived threat. For small doses, the immune system can initially accommodate this and, as a doses increase, the immune system will continue to adapt and build up antibodies to this allergen, i.e., the venom of the particular insect or snake or other such. These allergens associated with the venom immunotherapy are specifically associated with allergens that originate from the internal organs of animals, insects or reptiles.

[0006] Currently, most allergens associated with venom immunotherapy are not readily reimbursed when received from a pharmacist for the simple reason that the NDC code is not included in the database to which the pharmacist has access. Without an NDC code in the database, the pharmacist cannot access that information. By not being able to access information, the pharmacist cannot interface with a benefits provider for reimbursements nor can they have access to the Average Wholesale Price (AWP), which is the benchmark that has been used for many years for pricing and reimbursement of prescription drugs for both government and private payers. Initially, this AWP was intended to represent the average price that wholesalers used to sell medications to providers, such as physicians, pharmacies, and other customers. However, the AWP is not a true representation of actual market prices for either generic or brand drug products. AWP has often been compared to the "list price" or "sticker price", meaning it is an elevated drug price that is rarely what is actually paid. AWP is not a government-regulated figure, does not include buyer volume discounts or rebates often involved in prescription drug sales, and is subject to fraudulent manipulation by manu-

facturers or even wholesalers. As such, the AWP, while used throughout the industry, is a controversial pricing benchmark.

[0007] The AWP may be determined by several different methods. The drug manufacturer may report the AWP to the individual publisher of drug pricing data, such as Medi-Span. The AWP may also be calculated by the publisher based upon a mark-up specified by the manufacturer that is applied to the wholesale acquisition cost (WAC) or direct price (DIRP). The WAC is the manufacturer's list price of the drug when sold to the wholesaler, while the DIRP is the manufacturer's list price when sold to non-wholesalers. Typically a 20% mark-up is applied to the manufacturer-supplied WAC or DIRP, which results in the AWP figure.

[0008] The publishers then in turn sell these published AWPs to government, private insurance, and other buyers of prescription drugs, who use these data tables to determine reimbursement and retail prices. Because AWP is a component of the formulas used to determine reimbursement, elevated AWP numbers can drastically increase the dollar amount that government, private insurance programs, and consumers with coinsurance must pay.

[0009] Pharmacies typically buy drugs from a wholesaler and then sell them to the public. Many patients have coinsurance or copayments, where they only pay for a portion of their prescription cost. The insurance company then pays the rest of the cost (the reimbursement) to the pharmacy. Insurance companies include prescription benefit manager (PBM), health maintenance organization (HMO) or government programs, such as Medicaid or Medicare Part B or D. In addition, the pharmacy receives a dispensing fee for filling the prescription. Fees are, for example, set between $3 to $5 per prescription, but may vary by state.

[0010] Reimbursements are based on AWPs. However, pharmacies purchase drugs based on the WAC. The difference between the WAC (what the pharmacy actually paid for the drug) and the reimbursement from insurance (based on AWP) is known as the spread, and equates to the profit that the pharmacy receives.

[0011] Market pricing on brand drugs tend to be about 16.6 percent less than the AWP. However, the relation of AWP to generic pricing is not clear. Older generics tend to have a large spread between the AWP and WAC, which in turn gives a large spread, and higher profit margins for the pharmacy or other provider of the drug. Many payers, such as PBMS or HMOs, will determine a maximum allowable cost (MAC) pricing on generics to avoid being overcharged. Newer generic products, compared to older generics, may not have as favorable of a spread, thus the need for MAC.

[0012] Collusion between AWP publishers and wholesalers to artificially inflate the AWP, and in turn increase the spread, has led to court cases in the U.S. In these cases, it was alleged that increasing the spread benefited the wholesaler because customers (pharmacies and large institutions) were more likely to buy from them than a competing wholesaler where the spread was not as desirable. The publisher of AWPs profited because pharmacies were more likely to buy the pricing lists from the publisher that noted the higher AWPs used in calculating the spread, than to buy them from other publishers with lower AWPs. Due to this pricing fraud, many payers, including government payers, are no longer using AWP for pricing, and are switching to other more transparent pricing benchmarks, such as WAC or AMP (average manufacturers price). However, AWP may still be found in use in the U.S. because it has been the standard for decades.

[0013] However, in order for a pharmacist to access the AWP and to be able to interface with benefits providers, the product associated with an NDC must be in the database. Currently, nonvenoms are an item that does not exist in the database.

SUMMARY

[0014] In one aspect thereof, a method for adjudicating reimbursement for venom derived allergens between a pharmacist and a reimbursing entity is provided. The method comprises obtaining at a central control center National Drug Codes (NDC's) for a plurality of venom derived allergens at a defined concentration level, each NDC uniquely identifying that particular allergen as to its manufacture, the particular allergen, the packaging and the defined concentration level, and further obtaining information as to a description of the particular venom derived allergen, concentration level and manufacturer determining by the central control center an Average Wholesale Price (AWP) for each of the venom derived allergens associated with each of the NDC's, storing in a central control database the obtained NDC's in association with an associated AWP and associated information for the venom derived allergen, which associated information includes translation information to allow practitioners to determine from a desired diluted level and number of doses of a desired NDC carrying venom derived antigen and a known dilution procedure how to translate back to the amount of base concentration of the NDC carrying venom derived antigen used to create the desired diluted level and number of doses, accessing a third-party database accessible by a pharmacist and determining if any of the NDC's in the central control database are contained within the third-party database and, if not, transferring the associated NDC's not in the third-party database and that exist in the central control database for each of the venom derived allergens to the third-party database in association with the AWP and associated information for each of the venom derived allergens for each of the NDC's, and uniquely associating each of the NDC's in the third-party database to the central control center for adjudication information, and creating an adjudicating database at the central control center having defined benefits associated with reimbursable entities for each of the NDC's stored in the third-party database and in the central control database in association with the translation information for each of the NDC-carrying venom derived antigens, wherein a pharmacist can access this information by accessing a particular NDC in the third-party database to obtain information regarding reimbursable benefits from the central control center and enter the diluted level and number of doses and a claim with the central control center for adjudication of the amount of base concentrate venom derived antigen used and wherein the central control center is able to process any claim made by the pharmacist and reimburse the pharmacist accordingly for the base concentrate venom derived antigen used to provide the desired diluted level and number of doses of the desired NDC carrying venom derived antigen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] For a more complete understanding, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

[0016] FIG. **1** illustrates a general diagrammatic view of the overall interface of basic databases;

[0017] FIG. **1**A illustrates an NDA code;

[0018] FIG. **2** illustrates a diagrammatic view of a database that is populated by a central control system;

[0019] FIG. **3** illustrates a flow chart for the operation at the central control system for receiving NDCs from the manufacturer;

[0020] FIG. **4** illustrates a flow chart for the operation of populating third-party database by the central control system;

[0021] FIG. **5** illustrates a flow chart for the operation at the pharmaceutical location;

[0022] FIG. **6** illustrates a flow chart for the overall generation of the AWP and the interface with the benefit providers;

[0023] FIG. **7** illustrates a diagrammatic view of flow beginning at the prick test and following through to filling the prescription at the pharmacist location;

[0024] FIG. **8** illustrates a flowchart for interfacing with database for accessing benefits by the pharmacist;

[0025] FIG. **9** illustrates a flowchart for the parsing operation at the database for parsing non-NDC allergens to an NDC-bearing base concentrated allergen;

[0026] FIG. **10** illustrates a diagrammatic view of a dilution sequence of diluting a concentrated antigen extract;

[0027] FIG. **11** illustrates a process flow for diluting an antigen extract;

[0028] FIG. **12** illustrates a process flow for the overall distribution chain;

[0029] FIG. **13** illustrates a process flow for multiple extracts;

[0030] FIG. **14** illustrates an alternate embodiment of FIG. **13**;

[0031] FIG. **15** illustrates a flowchart for one example of processing a physician script;

[0032] FIG. **16** illustrates a diagrammatic view of a table in a relational database relating distributed doses back to NDC-bearing dose;

[0033] FIG. **16**A illustrates a diagrammatic view of a table showing the dilution procedure;

[0034] FIG. **17** illustrates a second example of that illustrated in FIG. **15**;

[0035] FIG. **18** illustrates a diagrammatic view of processing of a script received from a physician at a pharmacist to compound a patient-specific dosage;

[0036] FIG. **19** illustrates an alternate embodiment of that illustrated in FIG. **18**;

[0037] FIG. **20**A illustrates a diagrammatic view of a process of filling a script received from a position and FIG. **20**B illustrates a table associated with such process;

[0038] FIG. **21** illustrates an overall process flow illustrating the prick test, the script flowing through to the final patient does; and

[0039] FIG. **22**A illustrates a flowchart for parsing an antigen having a base dose with more than the prescribed antigens and FIG. **22**B illustrates a table associated with the parsing operation.

DETAILED DESCRIPTION

[0040] Referring now to FIG. **1**, there is illustrated a diagrammatic view of the overall system for transferring NDC's between systems. The NDC, or National Drug Code, is a unique 10-digit, 3-segment number. It is a universal product identifier for human drugs in the United States. The code is present on all nonprescription (OTC) and prescription medication packages and inserts in the U.S. The 3 segments of the NDC identify the labeler, the product, and the commercial package size. The first set of numbers in the NDC identifies the labeler (manufacturer, repackager, or distributer). The second set of numbers is the product code, which identifies the specific strength, dosage form (i.e, capsule, tablet, liquid) and formulation of a drug for a specific manufacturer. Finally, the third set is the package code, which identifies package sizes and types. The labeler code is assigned by the FDA, while the product and package code are assigned by the labeler.

[0041] For example, the NDC for a 100-count bottle of Prozac 20 mg is 0777-3105-02. The first segment of numbers identifies the labeler. In this case, the labeler code "0777" is for Dista Products Company, the labeler of Prozac. The second segment, the product code, identifies the specific strength, dosage form (i.e, capsule, tablet, liquid) and formulation of a drug for a specific manufacturer. In our case, "3105" identifies that this dosage form is a capsule. The third segment is the package code, and it identifies package sizes and types. Our example shows that the package code "02" for this bottle of Prozac identifies that 100 capsules are in the bottle. The FDA maintains a searchable database of all NDC codes on their website. This is illustrated in FIG. **1**A.

[0042] The NDC codes are unique codes that are applied for and assigned to specific individuals to be associated with specific products. Each manufacturer of allergens, for example, has a unique NDC associated with the product that they provide, which is assigned to that manufacture for that product based upon their applying for such. The manufacturer, therefore, has full ownership of that NDC. In order for that NDC to appear in a database with the associated information the approval of that manufacture is required. For example, a manufacturer of a well-known drug will provide information to the database and populate that database and the record associated with that NDC with the information regarding that product associated with that NDC but they will also define what the AWP is for that product. It is the manufacturer, not the person that controls the NDC of the manufacturer, that controls what is in database, including the AWP. Additionally, it should be noted that a distributor could actually apply for an NDC and could populate or associate with that NDC information regarding a particular product. They could actually place this NDC that they own, this being a unique NDC, in a database with another NDC, a different and unique NDC, that will be associated with basically the same product. This, of course, would provide some NDC contention within the database which is to be avoided if possible.

[0043] Thus, a manufacturer **102** has associated there with its own proprietary database **1044** to store their NDCs. This can be provided to a central control center **106**. The central control center **106** desires to have access to these NDCs of the manufacturer **102**. This is the primary reason that these NDC's do not exist in any other database. Typically, the central control center **106** would have some type of contractual relationship with the manufacturer **102** for the

purpose of maintaining some type of exclusivity with respect to the manufacturer's NDC. Thereafter, these NDC's are stored in a central control database **108**. In this database **108**, the central control **106** can modify the information. Primarily, the main aspect that they had is the AWP. This allows the central control **102** to control this AWP. There is, of course, the wholesale cost exactly charged for the product to an end user such as a pharmacist, but the AWP is the benchmark price. This is not necessarily the price that the pharmacist, for example, will charge to the customer but, rather, it is the benchmark price. Further, this is not even the price that will be reimbursed to the pharmacist even if the pharmacist billed the customer for such. Thus, of course, this would not result in any type of price-fixing; rather, all that is controlled by the central control **106** is the inclusion of AWP within the database. This AWP can be utilized by the reimbursing entities and the such for centering on a final reimbursement price.

[0044] In this disclosed embodiment, the data associated in with these venom derived allergens is then downloaded into a third party database **110** associated with a third-party information provider. This information provider is one of many information providers that provide access through a network **112** to a pharmacy **114**. It is noted, however, that the central control **106** first confirms that none of the NDC's associated with any of the venom derived allergens is actually currently in the third party database **110**. Once these NDC's and their associated information and associated AWP's are stored in the third party database **110**, the central database **108** has some control over both the information and the AWP associated with each of the NDCs. Thus, when a pharmacist receives a request from a physician to fill a prescription for a venom derived allergen for delivery to the physician, the pharmacist can access the third party database **110** and determine that this is, in fact, in the database and is a reimbursable prescription.

[0045] Referring now to FIG. **2**, there is illustrated a diagrammatic view of the third party database. This includes, in one column, NDC's, and a second column AWP's and in a third column information regarding the product associated with the NDC.

[0046] Referring now to FIG. **3**, there is illustrated a flowchart depicting the initial operation of populating the database **108**. The central control **106** initiates the process at a block **202** and proceeds to block **304** in order to receive the NDC from the manufacturer with the associated information regarding the associated product. This is one associated with product in the database of the control center **106** and also with products controlled by the control center **106**. The control center **106** is typically associated with some type of distribution center such that, in the information that they associate with the NDC in the database **108**, the control center **106** and the entity associated therewith are the distribution arm for that product, i.e., this is where the product is ordered from by the pharmacist. The program then proceeds to a block **308** wherein the AWP for that particular product and associated with that NDC is defined. This is a number that is set at whatever level is determined to be correct and appropriate by the control center **106**. There are a number of reasons for the price being set at any level. There is, of course, some cost of buying a product from the manufacturer **102**, the markup and expenses associated with the operation of the control center **106**, resulting in a wholesale price to the pharmacist. This wholesale price is not necessarily associated with the record that is stored in the database **110**. However, it is this information that is utilized in determining what the AWP will be for that NDC and associated product. A number of factors, of course, enter into that calculation, including practical knowledge of how the insurance industry reimburses for venom based allergens. After processing, the information is stored in the central control database **108**.

[0047] Referring now to FIG. **4**, there is illustrated a flowchart depicting the transfer of data, which is initiated at a block **404** and then proceeds to a block **406** to access the third-party database through the network **112**. The program then flows to a function block **410** to confirm that no NDCs in the control database **108** exists within that third-party database **110**. The program then flows to a function block **412** to populate the third-party database **110** with information from the control database **108**, which, as described above, includes the information from the manufacture, information regarding the central control center **106** as being a source of the product and the AWP for that product, all associated with the NDC for that product. The program that flows to a terminate block **414**.

[0048] Referring now to FIG. **5**, there is illustrated a flowchart for the operation at the pharmacy. This is initiated at a block **502** and then proceeds to a block **504** wherein the pharmacist receives a request from a physician for a venom derived allergen. This might actually be presented to the pharmacist by a patient which desires to receive the venom derived allergen for dilution and processing by the pharmacist or it may in fact be an already diluted venom derived allergen that could be actually self-administered by the patient. The program then flows to a decision block **506** to determine if the product is in stock. If the product is in stock, the program flows to a function block **512** to check the database for reimbursement and, if not, the program flows to a block **510** to process a stock item by whatever procedure the pharmacist utilizes. When checking the database, the pharmacist enters the NDC of the product, as indicated in a block **514**. The program then flows to a decision block to determine if the NDC is found, this being block **516**. If not found, the program exits and, if found, the program flows the function block **518** wherein the pharmacist can view the AWP for that product. This gives the pharmacist some idea as to what might be reimbursable, but also, the insurer itself will illustrate some type of potential co-pay. This just indicates the amount that the patient will pay at the counter. The pharmacist then can enter an amount that the pharmacist will claim that they want to be paid for this particular product. It may be less than the AWP but not more than AWP. This, of course, is a function of what the pharmacist desires. This is indicated by block **520**. Thus, there is provided a third-party database **110** having information contained therein, which is controlled by the central control center **106** with respect to the venom derived allergens. Part of this is the AWP and part of it is the source for that venom derived allergen. The insurer has access to this information and can utilize it to adjudicate a claim. Information from the insurer can be linked to this database indicating a co-pay, for example. With respect to this, and insurer can indicate that it will pay the entire cost of the particular venom derived allergen or indicate what percentage of the venom derived allergen that it will pay for. Sometimes, it is just a co-pay. However, for some very expensive venom derived allergens, the insurer may over time decide that it only pays a small

percentage of the venom derived allergen. This will be on an allergen-by-allergen basis. By allowing this third-party database **110** to be controlled by the central control center **106** with respect to the cost for the particular venom derived allergen, this allows central control center **106** to control the adjudication of the particular venom derived allergen. The Program then flows to a function block to send a request to the third-party payee for reimbursement, as indicated by block **522**.

[0049] The process for adjudicating any claim requires that some entity or party has worked with the insurance company or the reimbursing entity to negotiate the particular reimbursement or any benefits that are provided. If the pharmacist is apprised of an AWP in the database for a particular venom derived allergen, they at least have a price that they can charge for the product. For example, if the pharmacist has a product on the shelf with an NDC any position writes a prescription for that venom derived allergen, the pharmacist just needs to know how much to charge the patient. By accessing the third-party database **110**, the AWP can be determined. However, that alone doesn't allow the pharmacist to determine whether benefits are associated with that particular venom derived allergen. In order to do that, there has to be some link between an adjudicating party or entity. The pharmacist can select the NDC and a field (not shown) that directs the pharmacist to an adjudicating party or entity to provide information as to benefits that are available. If such indicates that benefits are available, then the pharmacist knows that they can make a claim to this adjudicating party.

[0050] In the current disclosed embodiment, the central control center **106** maintains the adjudicating database. The central control center **106** is responsible for interfacing with insurers and the such to provide these benefits. For example, if there are five major insurance companies that reimburse the pharmacist or even Medicare, the central control center **106** will make the arrangements for reimbursement and allow the pharmacist to determine whether the patient, who may be associated with any of these reimbursement entities, can receive benefits. If, for example, the patient had insurance with Insurer A, and central control center **106** had negotiated with Insurer A for certain benefits, this would be made available to the pharmacist. The benefits might provide for some type of co-pay which the pharmacist could charge to the patient and then the pharmacist could make a claim for the remaining value of the venom derived allergen to the adjudicating party, i.e., in this case the central control center **106**. The central control center **106** would then process the claim and forward a check to the pharmacist. Since the central control center **106** populated the third-party database **110** with all of the NDCs, the central control center **106** has exclusive rights to adjudicate these NDCs and the associated venom derived allergens. Thus, this unique link from the third-party database **110** to the central control center **106** allows all claims to be adjudicated therethrough because the central control center **106** has exclusive control over these NDC for these venom derived allergens.

[0051] All of the NDCs, as noted hereinabove, or for venom derived and allergens that are to be dispensed to a patient are a single dose venom derived allergen. Thus, each of the NDCs that would be obtained by the manufacturer would be for single dose venom derived allergens rather than bulk venom derived allergens that are currently provided.

[0052] FIG. **6** illustrates a flow chart depicting the operation wherein the control center is able to determine the AWP by interfacing with the benefit providers. This is initiated at a block **602** and then proceeds to block **604** wherein the control center assembles the various cost information regarding the manufacturers cost to the control center, the expenses of storing the venom derived allergen at the control center, i.e., where the control center is the distributor and provider of the venom derived allergen, and what kind of markup or profit margin the control center expects to receive on a venom derived allergen. The program then flows a function block **606** to determine the AWP. This AWP is based on the information retrieved in block **604** and then a ceiling for the AWP is determined. This ceiling is a number that is arrived at by the control center based upon their knowledge of how the benefit providers reimburse pharmacists and the such. Since the AWP is a ceiling and the pharmacist cannot charge more than that, they provide a number that is a benchmark for the industry. By determining this benchmark, the insurance industry will typically center in on a lower reimbursable price, depending upon how valuable they think a particular venom derived allergen or the such is to the industry. For example, if they sold the product for $350 to the pharmacist, this being the wholesale price, they might set the AWP at $500. Over time, pharmacist may actually make a claim for only $450 which, at first, the insurance copies may reimburse. After a time, the insurance industry may come to the conclusion that this venom derived allergen is only reimbursable at a rate of $400.

[0053] The program then flows to a function block **612** wherein a control center can interface with benefit providers to determine what the reimbursement levels are and, if necessary, adjust the AWP. However, they can also determine such things as rebate programs and incentives and the such that they can provide to the pharmacist, as indicated by a function block **614**. Since they control the database, they can also write information from the interface with that particular part of the database. The program then flows to a function block **616** to adjust the AWP if necessary and then into a function block **618** to adjust the information in the database if necessary.

[0054] The overall operation of initially testing patient at the physician's office, writing a script for the patient and completing the prescription by processing that script at a pharmacist location or some type of compounding pharmacy operation. In general, it must be noted that each script is very patient-specific; that is, in a system that is unique to testing for venom derived allergens, it is necessary to determine which of multiple antigens must be combined in a desensitization program. It may be that, for example, a prick test initially indicates that the patient is highly allergic to cat fur, dog care, various types of pollen, certain venoms, and the such. With a positive indication for these particular venom derived allergens, the physician can then determine which antigens need to be combined in some type of prescribed dosage regimen. Since there are so many venom derived allergens that can exist and since each patient is an individual, this combination can be somewhat daunting if the desire of the industry were to provide only that particular combination as a "drug" that has an NDC associated there with. This is practically impossible, of course.

[0055] Referring now to FIG. **7**, there is illustrated a flow diagram of the overall process of determining a particular

combination of antigens to desensitize an individual and the regimen therefore. This is initiated at a block **702** wherein the physician subjects the patient to what is known as a "prick" test. This prick test is a test whereby the physician introduces a small amount of venom derived allergens into a small area on the skin of an individual. There can be multiple spots that are arranged in a grid on, for example, a portion of the back of the patient. These allergen locations are recorded and then they are observed over a certain period of time. There is also typically some type of base allergen that is provided such as a hypoallergenic antigen and a hyper allergenic antigen such that there is an area that will result in no response and as an area that will result in a guaranteed response. Upon observation, areas that elicit a positive response indicate that the patient is sensitive to that particular allergen. It may be that the patient is very sensitive to certain of the allergens and just mildly sensitive to others. The physician then determines which of the allergens need to be included in a desensitization program. For example, if an individual in Texas showed a positive response to some allergen that rarely occurred in Texas, the physician might not include that in a desensitization regimen.

[0056] Once the regimen is set upon for a particular patient, a script is then written by the physician, as indicated by block **704**. This can be a script for a single venom derived antigen if that was all that was required for a desensitization program or it could be for a cocktail of multiple venom derived antigens. The physician will define the venom derived antigen or antigens that are to be included in the regimen, the dosage level and the carrier. For example, for the first desensitization level, the most diluted level of antigen will be utilized. Typically, the physician will require that the single venom derived antigen or cocktail of antigens be provided in a carrier such as saline or glycerol in a vial that will allow for a certain number of injections. It may be that the physician wants to prescribe for this first desensitization level a dosage that will allow for three injections per week for three weeks.

[0057] This script is then written and provided to the patient or it can be directly delivered to the pharmacist, as indicated by a path **706** to a block **708** indicating the pharmacist. The pharmacist then creates a patient-specific venom derived antigen cocktail, as indicated by block **710**. The pharmacist then lists the antigens that are contained within the cocktail, noting that there could be a single antigen. This is indicated at a block **712** and then the pharmacist accesses the database for price and benefits. This is basically the Pharmacy Benefits Manager (PBM) database, which contains all of the drugs, etc., that are available for reimbursement. If the pharmacist, for example, looks up a particular antigen that was prescribed in the script and does not find it, this indicates that it is not something that can be reimbursed. If, however, this antigen exist within the database, it indicates both the AWP for that antigen and benefits associated there with. All of this is pre-populated within the database. However, with respect specifically to any antigen, the NDC for that antigen will only be associated with the base concentrate level. The script, however, is for a particular diluted dosage of that particular antigen and even a combination of multiple antigens at that particular dosage. This database is accessed at a block **714** and then, after access is complete, as indicated by a decision block **716**, the prescription is filled at a block **718**. The operation of determining the particular AWP and benefits associated with any script for antigens at any dosage level, wherein the particular combination of antigens does not have particular NDC associated therewith nor does any antigen by itself have a particular NDC associated therewith, it is necessary to cross correlate this with an NDC that has an AWP associated therewith. Further, with respect to antigens specifically, the current NDC for any antigen is associated with the base concentrated material and this base concentrated material is too toxic to utilize at that concentration level. Thus, anything that is distributed to the patient will always be diluted from this base concentrated material. As will be described hereinbelow, it is always necessary to cross correlate any dosage level back to the NDC for the base concentrated material in order to determine benefits. Further, each of the scripts set forth by the physician will always have a list of each of the one or more allergens to which the patient exhibited a level of sensitivity thereto and the antigens associated there with. Further, the physician will determine the dosage level also. This is indicated by block **720**.

[0058] Referring now to FIG. **8**, there is illustrated a flowchart depicting the operation of accessing the database, which is initiated at a block **802** and then proceeds to a decision block **804**. The decision block **804** determines whether a request for access has been received and, if so, the flowchart proceeds to a block **806** to determine if the particular request of the PBM database is associated with that for an antigen. If not, the program will follow the "N" path to a block **802** to proceed along the normal benefit determining process. This is not described herein. If, however, the request is for an antigen, this is a specific operation, since the only NDC that exists is for a base concentrated antigen that is too toxic to be directly distributed to a patient or for another dosage level that is to be diluted. Once an antigen NDC as indicated, the program flows to a block **810** in order to receive the NDC for the base antigen or antigens and then to a block **812** to receive the dose level for all of the antigens, as well as the carrier and the dilution procedure that is utilized. The program will then flow to a block **814** in order to cross reference the particular dose level that was actually distributed to the patient to the dose of the highest concentrated level of the base concentrate material. This will be on a parsed operational level. This parsed operational level means that, for example, if **10** antigens were distributed in a cocktail, it would be necessary to cross reference the distribution of this particular dosage level to the actual material utilized from the NDC-carrying base concentrated level. If, for example, for a single base concentrated material that yielded an antigen in the cocktail mixed, required 1 mL out of a 50 mL bottle, the benefits for that one milliliter could be determined, as this is a "dosage" of the base concentrated level that is associated with an NDC. As indicated by a block **816**, the benefits can be determined for "each" allergen at a base or lowest concentrated level that is associated with an NDC. It is noted that an NDC might be provided for an already diluted level of a particular antigen. However, it is always necessary to determine what portion of the NDC-carrying material is utilized down to the final diluted level and then cross correlate this back to the NDC-carrying material at its particular dilutant level, this requiring some information as to the procedure for dilution, the carrier, etc. in order to adequately determine exactly how much of the NDC-carrying material was utilized. The program then

proceeds to a block **818** to then access the benefits and then to a block **822** to end program.

[0059] Referring now to FIG. **9**, there is illustrated a flowchart for the parsing operation, which is initiated at a block **902**. The program then proceeds to a block **904** in order to receive the prescribed script levels. The program then proceeds to a block **906** in order to parse antigens in the cocktail to individual antigens (noting that a single antigen could be provided for). The program then flows to a block **908** in order to cross correlate each of the parsed antigens and the script dose level back to the base concentrated amount, noting that this requires the carrier to be known, the procedure to be known for dilution. Since the script merely states that the most diluted level must be provided for, the pharmacist then to provide that particular antigen. The particular base concentrated antigen could be at different concentrated levels which would require a pharmacist to utilize one of multiple dilution procedures to obtain the final diluted level desensitization regimen. However, as will be described hereinbelow, it could be that physician prescribes a particular antigen in the cocktail that can be found in an antigen at a base concentrated level that contains multiple antigens. This is very common in the industry. For example, some companies deliver already mixed cocktails for various types of pollen. If the physician only prescribed one out of these types of pollen, then this procedure must be noted so that particular amount of base concentrated material, that can be reimbursed based upon its NDC, could be allocated. For example, if it were determined that 1.0 mL of the base concentrate pollen cocktail were required in order to get the prescribed amount of the one type of pollen, and this was from a 50 mL bottle, this would indicate a 1 mL dosage of the base concentrate level, but this would be divided by the number of particular antigens that are in the base concentrate material. If there were, for example, ten antigens contained in the cocktail, then this would be divided such that only $1/10^{th}$ of the dosage would be applied to benefits. That is, a 50 mL bottle would be considered as containing, assuming that the starting dosage is always 1 mL or any deleting process, as having 500 dosages of individual antigens. This, of course, requires knowledge of the dilution procedure, as indicated by a block **910**. Once the crosscorrelation is complete, the program proceeds to a return block **914**.

[0060] Referring now to FIG. **10**, there is illustrated a depiction of a technique for diluting immunomodulators such as antigens, as one example. Preparation of a diluted antigen is performed first by receiving a bottle of extract concentrates at a base concentrate level from an approved vendor. These are formulated in a given weight/volume (w/v) format with a given antigen associated therewith. For typical antigens such as those associated with the cat antigen, these are relatively well controlled. Typically, a vendor will provide an extract for a single antigen or allergen. Allergens such as pollen and the such are not as well controlled due to the technique for collecting such. In any event, there are typically very few approved vendors for these extracts and an allergist typically receives these vendor provided concentrates in a sufficient quantity to make the necessary diluted solution.

[0061] Allergen extract is typically comprised of a non-allergenic material, a non-allergenic protein and an allergenic protein. The extraction solutions can be aqueous containing saline and phenol work could be a glycerinated solution. The allergen is added, the units of measure are sometimes referred to as "AU" for "allergy units," typically used for mites. These are referred to as "AU/mL." For such things as grass and cat, the term "BAU" is used for "bio-equivalent units." For other allergens, the terminology is, for example, 1:20 w/v, which stands for 1 g source material per 20 mL of fluid. The relationship between BAU and 1:20 w/v depends upon the extract. In any event, there is a defined amount of extract contained within the concentrate.

[0062] When concentrated extracts are formulated by an authorized vendor, they are typically provided in standardized versions and non-standardized versions. In standardized versions, they typically are provided in a 50% glycerin dilutant. They can either be a single allergen extract or they can be a mix. For example, one can obtain a "9 Southern Grass Mix (concentrate)" which contains equal parts of: 2 Bermuda at 10,000 BAU/mL, P27 7 Grass at 100,000 BAU/mL, 15 Johnson at 1:20 w/v. For non-standardized extracts, these are typically provided in either a glycerin dilutant or an aqueous dilutant such as saline. They can be a single extract or a mix. Thus, whenever a concentrated extract is referred to hereinbelow, this refers to a formulation that is provided by an authorized vendor that can be diluted in accordance with the processes described hereinbelow. These are typically provided in the 50 mL bottles with a needle compatible.

[0063] Referring back to FIG. **10**, the extract concentrate is disposed in a bottle **1002**. This is a sterile concentrate that has an injection stoppered top **1004**. There are provided a plurality of five 5 mL sterile injection stoppered bottles **1006**, **1008**, **1010**, **1012** and **1014**, although there could be more and the bottles or containers could be larger than 5 mL. Each of these bottles has disposed therein a defined amount of dilutant, depending upon what the final required to be. Typically, the amount of dilutant is 4.5 mL. The procedure is to, first, extract a defined amount of the concentrated extract from the bottle **102** and dispose it in the bottle **1006**. This is facilitated by the sterile hypodermic that is inserted through the stopper at the top of the bottle **1002** to extract concentrate and then the hypodermic is inserted to the stopper in the bottle **1006** to inject extract from bottle **1002** into bottle **1006**. Typically, the concentration in the concentrated extract bottle **1002** is 1:20 w/v. This will result in a dilution of 1:10 in bottle **1006**. If the amount injected is 0.45 mL. Then, 0.45 mL of the diluted solution from bottle **106** is then extracted and inserted into bottle **1008**, resulting in a 1:100 dilution of the original concentrate in bottle **1008**. The process is repeated up to the bottle **1014** to provide a solution that is at a dilution of 1:100,000 of the original concentrate. This is a conventional way to provide a selected dilution of the original antigen. However, it should be understood that any concentration level can be provided from one bottle to the next. The purpose of using the sequential bottles is to allow an achievable portion of one bottle to be distributed to the next bottle, rather than trying to extract a very small amount of the initial concentrated extract. Typically, an allergist will then extract from the desired dilution an amount of the diluted antigen for injection percutaneously. Typically, desensitization is achieved by using the most diluted antigen level initially and sequentially moving up to a higher concentration level over time **1**.

[0064] Illustrated in FIG. **10** are three hypodermic needles, one selecting a "dose" from bottle **1014**, and labeled hypodermic **1016**, a second hypodermic needle **1018** for retrieving a dose from bottle **1012**, a third hypodermic needle **1020**

for extracting a dose from bottle **1010**. Each of the hypodermic needles **1016**, **1018** and **1020** will contain a different diluted dose. These would typically be separate needles in the event that the allergist or medical professional is injecting a patient. For other purposes, they could be the same needle, depending upon the dose or concentration required. A "dose" is defined as the amount of all the diluted product that would be required for the desired immunotherapy. This is defined by the medical professional. If, for example, bottle **1012** were utilized, it may be that 1 mL of diluted solution constituted a "dose." It could be that less than 1 mL constituted a "dose."

[0065] This entire procedure is provided as a "data" procedure which can be designed for particular carriers and the such. Additionally, the carrier could be a transdermal cream which could be mixed by the pharmacist. Any carrier that is able to contain one or more diluted antigens at any prescribed dilution level can be utilized.

[0066] Referring now to FIG. **11**, there is illustrated a process flow for the embodiment of FIG. **10**. This is initiated at a process block **1102** and then proceeds to block **1104** wherein a certain amount of concentrated extract is received from a vendor, this being a qualified or authorized vendor for the extract. This is typically at a predetermined concentrate level of, for example, 1:20 m/v. The process then flows to a block **1108** wherein a defined quantity of, for example, 0.45 mL is transferred to a 5 mL bottle which already has a quantity of 4.5 mL buffered saline solution disposed therein. The process then flows to a block **1110** to determine if this was the last dilution step needed, as described hereinabove, depending upon what level of dilution is necessary. If, for example, by steps of dilution are required for a particular patient, and all five steps would be processed. However, it is not necessary to do all five steps if an intermediate dilution is required. This essentially customizes the overall operation for a particular patient. Further, the industry is so regulated such that only 5 mL bottles can be utilized for this dilution process. Thus, it will only be a maximum of 5 mL of diluted material available at any step prior to proceeding to the next step. Thus, if all 5 mL are required, then the next step is not desired or useful. If it is not the last dilution step, the process flows to a block **1112** to extract 0.45 mL of diluted antigen from the current 5 mL bottle and then flows back to the input of the process block **1108** after incrementing the bottle count at a block **1114**. This continues until the last dilution, at which time the process flows from the block **1110** to a terminate block **1116**. Again, any type of carrier could be utilized and bottles larger than 5 mL could in fact be utilized. This all depends upon the number of "doses" at a particular diluted level that are required by the physician right the initial script or prescription.

[0067] Referring now to FIG. **12**, there is illustrated in overall flow of the operation of moving concentrated antigen from a vendor to an end user via a pharmacist. As noted hereinabove, the liquid antigen in a concentrated extract at the base concentrate level that has associated there with an NDC was first received from a vendor that assigned that NDC, which is basically a combination of a single antigen or antigens suspended in a sterile agent. This is indicated by a block **1202**. The antigen is then diluted by the pharmacist from this extract to a desired diluted level, as indicated by a process block **1204**. This is combined in a block **1206** with a sterile carrier and containment material, i.e., sterile saline solution or, even a transdermal cream, for distribution to a patient. This, as described hereinabove, will typically be a defined number of doses of a single diluted antigen or multiple diluted antigens, wherein a dose is again defined as being a typical dose that a medical professional would administer to a patient in an office visit necessary to achieve a therapeutic result for which a patient could administer to themselves. This is either transferred as a combined antigen (diluted)/encapsulation product for storage on a shelf, as indicated by a block **1212**, or it would be transferred to a medical professional for a patient for management and disposition.

[0068] Referring now to FIG. **13**, there is illustrated a diagrammatic view of three different extracts of antigens/allergens **1302**, **1304** and **1306**. Each of these is for a particular antigen or allergen. The first two are for antigens respectively associated with a cat and a dog. The third is for an allergen associated with pollen. They are each diluted in accordance with the process described hereinabove with respect to FIG. **10**. As illustrated, the antigen extract in bottle **1302** is transferred as a diluted level to either an encapsulation material in a container **1310** or **1312**, each at a different diluted level. This is similarly the case with respect to the antigen in bottle **1304** and the allergen in **1306** wherein the diluted level of the antigen in the bottle **1304** is disposed in containers **1314** and **1316** and the diluted level of the allergen in bottle **1306** is disposed in containers **1318** and **1320**. Typically, any extract will be 100% pure with respect to the particular extract. These concentrated extracts are not typically mixed, which is typically a function that the medical professional or compounding pharmacist will perform. This, of course, is a customized mixture for a particular patient, i.e., this is a patient-specific combination as defined by the medical professional in the script provided to the pharmacist. For storage on the shelf, the operation of FIG. **13** will be facilitated in order to ensure that the containers **1310-1320** contained only a single antigen. Thus, when transferring the container to a store, for example, this would be stored on the shelf as a single allergen combination of the base concentrate level.

[0069] Referring now to FIG. **14**, there is illustrated an alternate disclosure to that of the embodiment of FIG. **13**. In this embodiment, each of the immunomodulators or antigens at the concentrated levels in the bottles **1302-1306** are diluted in accordance with the process noted hereinabove wherein they are sequentially diluted in the associated 5 mL bottles. However, note that only a maximum of 5 mL can be extracted from a given bottle at the last dilution level. If, in this example, it is desired to distribute a predefined number of doses to a final carrie having a fixed amount of carrier such as saline disposed therein and each dose added to that material will provide the final overall dosage or, alternatively, a viscous transdermal cream can be utilized that is initiated at an original fixed value in grants such that each dose will be associated with a single gram of that transdermal cream material, and then the amount of diluted antigen must be adjusted such that single dose is contained within 0.3 mL of the material. Thereafter, if 3 mL of antigen is extracted from a given bottle, this constitutes **10** doses such that a single dose will be associated with a single dose of the final encapsulation material. In this example, from each of the last dilution bottles for each of the concentrate bottles **1302-1304**, 3 mL is extracted and inserted within the container **1402** containing prescribed level of carrier material, be that saline solution or a transdermal cream. Thus, for each

milliliter of saline solution, for example, or each gram of transdermal cream material, there will be a single dose of the particular antigen associated there with. Thus, the carrier material in the container **1402** now acts as a consolidator of all of the antigens for a cocktail.

[0070] Referring now to FIG. **15**, there is illustrated a flowchart depicting one example of the generation of a script for a single antigen and filling of that fiction based on that script and getting reimbursed therefor. This is initiated at a block **1502** and then proceeds to a block **1504** in order to prepare the physician script for a single antigen. The program then flows to a block **1506** in order to define the requirements of the maximum dilution for the initial desensitization. The physician defined at which level the script is written for. For example, the physician sets forth a regimen. This regimen defines six levels of dilution of a defined NDC base concentrate antigen, each level of dilution are required for a predetermined amount of time. For example, the most diluted level might be required to be administered in three doses per week for three weeks for total of nine doses. The first script would require the pharmacist to deliver to the patient a vial containing nine doses at that diluted level of the at least a single antigen. The physician could then require the second higher level to be provided over the course of one week at three doses per week. This might require a second script to be filled by the pharmacist or, alternatively, the pharmacist could fill that script that same time and maintained that particular vial on the shelf for distribution to the patient at a later time, all of this depending upon the script provided by the physician. Of course, the physician could require the patient to come into the office for observation and then write another script. This would be a separate and distinct operation and prescription which would be independently associated with a different set of benefits possibly.

[0071] After the dilution level is determined for the initial desensitization or at any level in the desensitization regimen, the program flows to a function block **1508** wherein the pharmacist selects concentrate antigen and then goes to the dilution process required in order to achieve the desired diluted level. The program then proceeds to a function block **1510** wherein the pharmacist enters the NDC code for the base concentrate level and the script level. Basically, what the pharmacist does is enter the antigen name and the dosage level provided by script. The program then proceeds to a function block **1512** in order to perform a lookup in the PBM database for the particular antigen that is associated with the script. This lookup does a correlation, as will be described hereinbelow, to the lowest concentrate level having an NDC for that particular antigen. Knowing the dilution level and the procedure, it is possible to determine what amount of the NDC-carrying concentrate level for that particular antigen was utilized and then a reimbursement obtained therefor. This is indicated by the function block **1514** and **1516**. The program then flows to an initial End block **1518**.

[0072] Referring now to FIG. **16**, there is illustrated a table for a single antigen and the overall crosscorrelation information. This is a relational database. In this table can be seen that there is provided a column for the NDC code which is populated for a particular antigen. This indicates the name of the antigen and also information associated there with. There is also a dilution procedure for multiple procedures that can be associated with administering this particular antigen. Since the NDC code is not associated only with the type of antigen but also the concentration levels, this will be associated with the dilution level to determine what the various dilutant levels are in the overall standard process. As noted, the base level is indicated by a dilutant level D1 or a base concentrate level there than provide five additional dilutant levels D2 through D6. Each one of these dilutant level columns has associated there with a particular range of dilutant levels. As indicated by example, there are levels 1 through 3 for each of diluted levels, with more possible. Therefore, if the most diluted level, D6 were selected and that the procedure required that the dilutant level Z6 for the dilutant level column D6 were selected as the end dilutant level that was required by the physician in the script provided to the pharmacist, this would be what was put into the PBM system. However, there is no NDC associated with this particular antigen at this particular dilutant level. Therefore there must be some crosscorrelation back to column D1 for the base concentrate level, which column has an NDC associated there with. If the final dilutant level was Z6, this could be cross correlated back within the same row to the dilutant level Z1 of the base concentrate. However, although not shown, there could actually be multiple rows associated with the dilutant level Z6, one for each dilution procedure. Thus, the crosscorrelation from the antigen at a dilutant level back to the amount of bass constitute antigen required to process through the diluting procedure requires knowledge of the diluting procedure. This is illustrated in FIG. **16**A, wherein each column for the dilutant level D6 has three procedures such that there are provided three different amounts of the base extract that would be required, Z1, Z1' and Z1". For example, it might be that this requires corresponding levels of 0.8 mL, 1.0 mL or 1.1 mL for those three different levels in order to accommodate the three different dilution procedures S1, S2 and S3. Thus, it is not just a mere crosscorrelation operation but, rather, and overall knowledge of the process that is required in order to determine how much actual product was utilized of the original base NDC-carrying antigen. Only when the amount of the base concentrate NDC-carrying antigen that is utilized is known can the actual dosage be determined. For reimbursement purposes, it is important to know whether 0.8 mL, 1.00 mL or 1.1 mL of the base concentrate NDC-carrying antigen is utilized. Reimbursement is calculated based upon this. However, all that is necessary for the pharmacist to do is to put in the end product that was generated and the procedure for coming up with that end product and relate that to the NDC of the antigen that was utilized.

[0073] Referring now to FIG. **17**, there is illustrated a flowchart for a second example for preparing a script for a cocktail, which is similar to the flowchart of FIG. **15**. This is initiated at a block **1702** and then proceeds to a block **1704** to generate a script for a cocktail which is a patient-specific cocktail based upon a prick test performed. This is unique to that patient for that particular time. The program then proceeds to a function block **1706** in order to provide in that script a list of the antigens to be placed into the cocktail by the pharmacist, the final dilutant level of each, the dosage and the particular carrier. The program then flows to a function block **1708** in order to select the procedure that the pharmacist will utilize to provide this final diluted product with the prescribed number of dosages. This might be prescribed by the physician or it might be selected by the pharmacist. The program then flows to a function block **1710** wherein the pharmacist performs the dilution operation and then combines various antigens into the cocktail, at a

block **1712**. The program then proceeds to a function block **1714** wherein the NDC for each antigen is entered into the database, the dose level and the procedure. The program then proceeds to a function block **1716** to parse the particular antigens at the database, this parsing required in order to process each antigen in the database separately, as there must be a crosscorrelation back to each individual antigen, since only each individual antigen has an NDC associated there with. The program then proceeds to a function block **1718** in order to correlate the antigen back to the lowest concentrate NDC-carrying level, as described hereinabove with respect to the embodiment of FIGS. **15** and **16** and then to a function block **1720** in order to define the benefits and then to a function block **1722** in order to end the program, after the cocktail has been distributed to the end user such as the patient or the medical professional.

[0074] Referring now to FIG. **18**, there is illustrated a process, which is similar to that described hereinabove, for creating a cocktail from three different base concentrate antigens **1302**, **1304** and **1306**, referring hereinabove to the description with respect to FIG. **13**. These are diluted down in five separate steps to a final dilution level D6. In a first operation, there is provided a final vial **1802** that receives the final dosage from each of the processes for diluting the initial base concentrate levels. It may be that each of the final vials D6 each have 5 mL contained therein. By containing no carrier material in the final vial **1802**, 3 mL of each of the extracts can be placed therein resulting in a vial with 9 mL therein. If the physician prescribed the regimen to deliver a 1 mL dose of this concentrated level three times per week for three weeks, this would require nine doses and thus 9 mL of the cocktail. This overall process, for example, would require the pharmacist to understand each step of the dilution process to arrive at the final diluted. Thus, the pharmacist would indicate that there were three antigens in the final vial **1802** and that they were at the concentrate level D6/D6/D6. This would be provided to the PDM database. With this information alone, the system at the PDM database can cross correlate this back to the exact amount of base concentrate level lies for each of three base concentrate antigens **1302**, **1304** and **1306** utilized.

[0075] Alternatively, there is provided a vial **1804** which is the result of a different selection of cocktails from the D4 level. This, again, would have the three antigens in the concentrate level D4/D4/D4. This would again be provided to the PDM database which would then, based upon the dilutant level for each of the antigens and the procedure utilized to achieve that dilutant level to relate this back to the antigens utilized at the lowest NDC-carrying concentrate level. If, for example, this vial **1804** resulted in 9 mL of material but the physician only required three doses of 1 mL each for two weeks, this would only require 6.0 mL. The pharmacist might only dispense 6 mL out of the 9 mL to the patient or professional. Even though three doses were distributed or 6.0 mL, this 6 mL of final product of D4/D4/D4 of Cat/Dog/Pollen, for example, or a venom derived antigen, antigen has to be related back to the original antigen value.

[0076] In an alternate embodiment, there is a vial **1806** provided that has been provided where in it receives diluted antigens from slightly different vials. In this operation, the three antigens are D5/D6/D6 and this is provided back to the PDM database. Of interest is that all three vials **1802**, **1804** and **1806** will each be input to the PDM system with their procedure and the result will be that, for this example specifically, that the reimbursement be the same, as the starting dilutant will be identical. This is procedure specific and script specific, with the cocktail noted as being patient-specific.

[0077] Referring now to FIG. **19**, there is illustrated an alternate embodiment wherein each of the base antigens **1302**, **1304** and **1306** are subjected to a different procedure wherein each of the original starting amounts are input to a first diluting vial **1902** and are subsequently diluted through vials **1904**, **1906**, **1908** and **1910** to a final vial **1912**. This is then distributed to the patient. This final vial represents the dilution at the vial **1910**, which is D6/D6/D6. This, along with this procedure, is then transferred to the PDM database, as indicated by block **1920**, which is then parsed to the specific antigens and into a translator associated with each antigen, indicated by a "X" for the crosscorrelation operation, blocks **1922**, **1924** and **1926** associated with the Dog, Cat and Pollen antigens, or venom derived antigens, which will then define the reimbursement. Each translation block **1922** will be associated with a reimbursement database for defined benefits associated with the particular antigen. Of course, it is important to know the amount of antigen that was actually utilized in the overall procedure which, again, requires knowledge of the final script dilutant level of the antigen delivered to the patient and procedure for obtaining that diluted level.

[0078] Referring now to FIG. **20**A, there is illustrated a diagrammatic view of an overall process where in the NDC is associated with an intermediate level of dilutant. In this embodiment, the dilutant level D4 is illustrated as having an NDC associated there with, as well as the base concentrate level of Thus, it is possible that the reimbursement and be defined back to this intermediate concentrate level. This is indicated in a table in FIG. **20**B, wherein the table can have associated with original diluted levels D4, D5 and D6 crosscorrelation relationships with respect to the base concentrate level but, in this table, there are only three diluted levels required, the dilutant level for vial D4, the vial D5 and the vial D6. If the concentrate level at the final vial was X3 based upon the NDC code being at vial D4, all that would be required is to do a crosscorrelation back to the dilutant level required from the vial D4. This would be for each of the dilutant set was combined in a vial **2002** from each of the antigens in the script, this indicated as being the antigens A1-N.

[0079] Referring now to FIG. **21**, there is illustrated a process for mapping prick test to the script. As illustrated, there is provided a diagram of the prick test, indicated by a reference numeral **2102**. This diagram **2102** indicates the locations of the particular allergens that were administered to locales on the person of the patient. This diagram illustrates the results with a "P" indicating a positive reaction and that an "X" indicating a negative reaction. Thus, the "P" indicates a sensitivity that must be considered in the script. Of interest is that the particular manufacturers of antigens might have a cocktail already existing in the base concentrate. This is illustrated with the bottom three test associated with antigens A(n−2), A(n−1) and AN. These are the last three antigens in the list. Of these, the last two are positive and the third for the last is negative. However, the script will have to include only the last two for the patient-specific script but the pharmacist only has the cocktail of all three available to them. Thus, the script will have a A0, A1, A3, A4 . . . , A(n−1) and AN as the antigens that are required for

the desensitization regimen. This will be provided to the pharmacist which will then select NDC-carrying antigen bottles A0, A1, A3, A4 . . . , And finally a bottle **2102** containing A(n−2), A(n−1) and AN, wherein only A(n−1) and AN are required in script to fill the prescription. This is then processed to provide the final patient dosage in the cocktail in the vial **2104**.

[0080] Referring now to FIG. **22**A, there is illustrated a flowchart depicting the overall parsing operation before the operation of FIG. **21**A. In this operation, if the base NDC has a greater number of antigens than the script, a decision block **2202** will determine such and flow to a block **2204**. The program will then flow to a function block **2206** in order to determine the base dosage for the script as required by and set forth by the physician of the antigens with the particular NDC, even though that NDC is associated with more than the antigens required by the script. The program then flows to a function block **2208** in order to determine the benefits. This is illustrated best with respect to the table of FIG. **22**B. Here, it is illustrated that there are three procedures for providing the end dilutant level at the vial D6 for each of the antigens in the cocktail antigen vial **2102**. If a certain amount of antigen is extracted from this particular vial **2102**, it will contain all three antigens. At a particular concentrate level at the level D6, this will yield the necessary concentrated level of the two antigens desired even though the third antigen is included. Since the final dilutant level is known for the two prescribed antigens, they can be cross correlated back to the amount of antigen that was actually extracted. However, for example, if 3 mL of the extract in vial **2102** were extracted, this might represent a particular portion of a 100 mL bottle and, if all three antigens have been prescribed, this would be the basis for the reimbursement. However, if only two antigens were prescribed, only two thirds of that prescribed extract would be reimbursed. Thus, by utilizing known script at the known dilutant level, this can be cross correlated back via the standard procedure (or whatever procedure is utilized) to what was actually utilized of the NDC-carrying base concentrate material to actually derive the final prescribed and delivered antigen to the patient.

[0081] Although the preferred embodiment has been described in detail, it should be understood that various changes, substitutions and alterations can be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A method for adjudicating reimbursement for venom derived allergens between a pharmacist and a reimbursing entity, comprising:

obtaining at a central control center National Drug Codes (NDC's) for a plurality of venom derived allergens at a defined concentration level, each NDC uniquely identifying that particular allergen as to its manufacture, the particular allergen, the packaging and the defined concentration level, and further obtaining information as to a description of the particular venom derived allergen, concentration level and manufacturer;

determining by the central control center an Average Wholesale Price (AWP) for each of the venom derived allergens associated with each of the NDC's;

storing in a central control database the obtained NDC's in association with an associated AWP and associated information for the venom derived allergen, which associated information includes translation information to allow practitioners to determine from a desired diluted level and number of doses of a desired NDC carrying venom derived antigen and a known dilution procedure how to translate back to the amount of base concentration of the NDC carrying venom derived antigen used to create the desired diluted level and number of doses;

accessing a third-party database accessible by a pharmacist and determining if any of the NDC's in the central control database are contained within the third-party database and, if not:

transferring the associated NDC's not in the third-party database and that exist in the central control database for each of the venom derived allergens to the third-party database in association with the AWP and associated information for each of the venom derived allergens for each of the NDC's, and

uniquely associating each of the NDC's in the third-party database to the central control center for adjudication information; and

creating an adjudicating database at the central control center having defined benefits associated with reimbursable entities for each of the NDC's stored in the third-party database and in the central control database in association with the translation information for each of the NDC-carrying venom derived antigens, wherein a pharmacist can access this information by accessing a particular NDC in the third-party database to obtain information regarding reimbursable benefits from the central control center and enter the diluted level and number of doses and a claim with the central control center for adjudication of the amount of base concentrate venom derived antigen used and wherein the central control center is able to process any claim made by the pharmacist and reimburse the pharmacist accordingly for the base concentrate venom derived antigen used to provide the desired diluted level and number of doses of the desired NDC carrying venom derived antigen.

2. The method of claim **1**, wherein the base concentrate NDC-carrying antigen is any concentration level that is too toxic for a patient to be exposed to.

3. The method of claim **1**, and further comprising the step of a physician creating a script defining a desired diluted level and number of doses of the desired NDC-carrying venom derived antigen.

4. The method of claim **3**, wherein the desired diluted level and number of doses of desired NDC-carrying venom derived antigen includes a script defining a desired level and number of doses of a plurality of NDC-carrying venom derived antigens to be included within each dose.

5. The method of claim **3**, and further comprising diluted by a pharmacist the NDC-carrying venom derived antigen to the desired level and number of doses defined by the created script by the physician.

6. The method of claim **1**, wherein the translation information includes a table of dilution levels of the NDC-carrying venom derived antigen close the associated with a plurality of dilution procedures wherein each dilution level defines a number of doses at that dilution level and, via the known one of the plurality of dilution procedures, the amount of base concentrate NDC-carrying venom derived antigen required yield that desired dilution level and number of doses.

7. The method of claim 6, wherein each of the NDC-carrying the venom derived antigen is defined as being able to be distributed in discrete quantities, each of the discrete quantities associated with a starting level of NDC-carrying venom derived antigen and each of the discrete quantities adjudicatable.

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